Exhibit – B / Expert Reports

Michael Mirando

From: WarLawyer@aol.com
Sent: Thursday, March 2, 2017 6:38 AM
To: mike@holterlabs.com
Cc: warlawyer@aol.com
Subject: Initial expert review report
Attachments: Arriego report.pdf

We will discuss this today. Both good and bad but a lot of work for the government to prove the case

Kevin Barry Mc Dermott, Esq,

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(please note – as of February 2, 2015, our building address changed from 8001 Irvine Center Drive to 300 Spectrum Center Drive due to a local street readdressing. This is an address change only, not a physical relocation of our offices.)

DRAFT – PRIVILEDGED AND CONFIDENTIAL WORKPRODUCT
PREPARED BY M. ARRIGO
OBSERVATIONS ON DISCOVERY DOCUMENTS – US. v. MIRANDO
DRAFT 1 – NOT A COMPLETE ANALYSIS

PRELIMINARY FINDINGS FROM DOCUMENT PRODUCTION
US. V MIRANDO

PREPARED FOR ATTORNEY MCDERMOTT

PRIVILEDGED AND CONFIDENTIAL WORK PRODUCT IN FEDERAL CASE
DRAFT – NOT INTENDED FOR DISCOVERY PRODUCTION

DATE PREPARED:
MARCH 1, 2017

MICHAEL F. ARRIGO

NOT A COMPLETE OR FINAL ANALYSIS

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Incomplete or inconclusive Analysis by FBI

FBI Surveillance states Mirando has several registered firearms, but the purpose of the surveillance is to establish his "morning routine" "which car he drives." None of those observations are noted, simply that FBI has firearms.

Why, if the purpose was to observe his routine does the report contain a note regarding firearms and no documentation of his morning routine.

Document drafted by Caleb Williams 5/6/2016

Interview with Patient Belen Perazzo Barber

There are several patient interviews that I have reviewed. I used patient Barber as a test and conducted an audit trail of his statements back to anything that corroborates his statements with regard to medical documentation and found none.

I searched Aetna records produced by the FBI and found a spreadsheet but nothing that states that Aetna produced it.

According to Barber she had one cardiac test but there is no documentation from a physician or provider of any kind corroborating this. Patients in my experience can forget their treatment regimen and appointments which is why providers do reminders. The Interview was conducted around the date of entry by the FBI of the report, April 9, 2014.

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Cross Check with Aetna Records for Patient Belen Perazzo Barber

I checked Aetna claims report and I do find claims for this patient but they are over four years prior (see below).

1/19/10
1/12/10
1/16/10
1/19/10
1/13/10
1/23/10
1/12/10
1/12/10
1/16/10
1/19/10
1/16/10

1/13/10

Medical Necessity of Treatment Frequency for Patient Belen Perazzo Barber

It may be possible that a cardiologist would prescribe this regimen. I can discuss to some extent in an expert report regarding medical documentation, coding, billing and insurance policy, but in the end the best criteria would be:

1. Independent medical opinion of a cardiologist
2. Based or supported by this patient's records which we don't have to my knowledge. That is the litmus test for whether these medical bills were appropriate or not
3. For any EEG (brain) prescribed services, the opinion of a neurologist

FBI Interview with Jon Barron, Founder of Datrix

Much of the case hinges on whether EEG and ECG may be performed with the same device and what determines whether that is possible to do with one device. Of the 60,126 pages in this case that I can review, one phrase here is all the FBI appears to have and it does not appear to be a certainty that the device cannot do both EEG (brain) and ECG (cardiac / heart) related monitoring.

Based on my own observations these two practices are converging since both are valuable indicators of a patient's condition. There are published studies I can cite.

This statement to me does not satisfy the 'reasonable degree of certainty test':

"BARRON believes that the DR512 model's sampling frequency rate is not sufficiently high enough to be used for an EEG. An EEG generally requires a higher sampling frequency rate than the model is capable of performing. Datrix also did not put in its FDA filing that performing an EEG was an intended use of the device. BARRON noted that the software used on the data collected from the DR512 would make no difference in whether or not an EEG could be conducted, since the device itself isn't able to sample data sufficiently for the test."

There also appears to be some confusion by the FBI on how to substantiate their case:

"Datrix has not filed with the FDA that an intended use of the DR512 model was to perform microvolt T-wave alternans [sic] for the assessment of ventricular arrhythmia"

This type of monitoring has nothing to do with EEG it is ECG related.

I will elaborate in our phone call.

Intricon Subpoena Production

There are grand jury subpoenas from the FBI but no damning production that I can see from Intricon

Lynn Medical Subpoena Production

There are grand jury subpoenas from the FBI but no damning production that I can see from Lynn Medical. Merely inquiry emails from Mr. Mirando.

Weaknesses in the Government's Case (Preliminary Observations)

1. I do not believe the Government has clearly established that the devices cannot do brain scans (EEG). There is much more to discuss this is only a quick briefing for you to determine next steps.
2. I do not believe the Government has clearly established without reasonable doubt that the billings are inappropriate.
3. The only way to clearly establish fraud or the absence of fraud is to look at the patient's medical records, what was prescribed by a physician, then the coding, billing and the payor's policies. We already know that there were few or no denials of insurance claims.

Next Steps – Discussion Points

1. Discuss time and resources to be applied
2. Discuss strategies and experts and how I can rely on those experts for my testimony
3. Additional records to review

EXHIBIT A

October 9, 2017

Mr. Ed Robinson
Attorney at Law
21515 Hawthorne Boulevard, Suite 730
Torrance CA 90503

Re: *US v. Mirando*

Dear Mr. Robinson:

Attached please find my report regarding loss calculations. You requested that I serve as a rebuttal expert to:

I. Review the medical billing, medical and other relevant documents, facts, indictment counts, summary of evidence, and provide:

1. Opinions on the validity of the Government's methodology to prove fraud; (determine which data is or is not fraudulent on a claim-by-claim basis to add it up and accurately calculate total loss).

2. An overview of the types of alleged fraud and any errors in the Government's methodology to prove what amount of fraud was caused by Mr. Mirando;

II. Review the Presentence Investigation Report developed under the U.S. Sentencing Guidelines (USSG) §2B1.1 standard, evaluate it using U.S. Sentencing Commission (USSC) methods and my knowledge training education and experience in the healthcare insurance and provider industry, and provide findings regarding loss.

I specifically reserve the right to add to, amend or subtract from the report as new evidence becomes available or the opinions of other experts are reviewed and considered.

Based on the information available to me with a reasonable degree of certainty:

1. The PSR / PIR has mathematical errors of 6% to 12% in the summation of Counts 1-15 of fraud (*see* Conclusions, page 52).

2. There are only seven (7) patients analyzed in the indictment and four (4) in the PIR / PSR which represent 137 claims out of over 31,000 claims in the data produced by the Government (*see* Conclusions, page 52).

3. The Government's methodologies do not form the basis for a statistically valid method to extrapolate to over $7 million in fraudulent bills and $2 million in fraudulent receipts and results in a 19% certainty level regarding total fraud rather than the industry standard of 51% reasonable degree of certainty (*see* Conclusions, page 52).

4. Duplicate charges are overstated. There are 90 actual duplicates which could be fraud or could be simply duplicate requests for payment. There are over 31,000 claims and a small percentage of these claims are 'adjacent' to each other by date of service (*see* Conclusions, page 52).

5. There were no audits conducted by any insurance company that confirmed the existence of fraud, and I have no data to conduct a statistically valid sample and project fraudulent claims in a damages analysis, beyond $10,695.06 (*see* Conclusions, page 52).

6. It appears inconclusive which device was used to perform alleged fraudulent 'unable to perform' procedures (*see* Conclusions, page 52).

7. Without a complete analysis of physician interviews, patient documentation and diagnosis, claims data and reimbursement tied by individual medical service, it is impossible to determine how much if any fraud was committed beyond seven patients analyzed (*see* Conclusions, page 52).

8. Based on the information available to me, I do not know if Mr. Mirando or others submitted the insurance claims produced by the Government, but in total Holter Lab's cannot in my opinion be held to damages or loss calculations beyond the amount of $10,695.06 (*see* Conclusions, page 53).

9. Since the suspect and duplicate claims are unproven in my opinion to be fraud, $2,587,360.23 for these amounts, minus $1,339.180.04 in unpaid claims as an offset, minus $538,515.73 in unproven duplicates, minus $2,574,940 for unable to perform procedures, plus the accurate fraud counts mathematical total of $10,695.06 equals a negative number of ($1,854,580.95) which means that subject to further audits, the payors (health insurance firms) in this case may owe Holter Labs for unpaid claims.

United States of America, Plaintiff, v. Michael Mirando, Defendant
Rebuttal Expert Report Regarding Loss
Prepared by Michael F. Arrigo, October 9, 2017

		Billed	Intended Loss	Paid (Actual Loss)	Total
Suspect + Dup		$8,008,875.45	$2,482,751.39	$ 2,587,360.23	$ 2,587,360.23
Less : Unpaid				$ 1,339,180.04	$ 1,339,180.04
		Subtotal - Suspect + Duplicates Less Offset			**$ 1,248,180.19**
Less: unproven duplicates					$ 538,515.73
		Subtotal - Above Less Unproven Duplicates			**$ 709,664.46**
Less: unproven unable to perform					$ 2,574,940.47
		Subtotal - Above Less Unproven Unable to Perform			**$ (1,865,276.01)**
Add: accurate mathematical total for Counts 1-15					$ 10,695.06
		Negative number means payors owe Holter Labs			**$ (1,854,580.95)**

Figure 1 - Summary of Calculations, with Mathematical Corrections by Arrigo

In my opinion net damages are zero (mathematically a negative number which may indicate payors owe money for unpaid claims). Though in my opinion the Government methodology could have been stronger, I have left the amounts of $10,695.06 (the correct mathematical total) my calculations (*see* Conclusions, page 53).

10. I am also aware from other loss and damages calculations where I was retained by counsel for the Relator in San Francisco that the 'foreseeable' loss in health care fraud cases, is the amount billed to an insurer, if not rebutted, however, the parties may introduce additional evidence to support arguments that the amount billed overestimates or understates the defendant's intent (*See* U.S. v Popov and U.S. v. Prakash).[1] (*see* Conclusions, page 53)

11. Therefore, in my opinion the actual, foreseeable amount of fraud is at most 31% of the billed amounts based on widely known industry practices and even data published by the Government itself (*see* Conclusions, page 54).

12. Intended fraud in this case is, at most 31% of the billed amount, and it is not reasonable to add 18 points to the sentencing guideline formulas, and, based on the statistically

invalid and unreliable methodology employed by the Government the payors in this case may owe Holter Labs money (*see* Conclusions, page 54).

13. The PIR / PSR states in paragraph 37 that the unable to perform payments are $3,025,329.47 and that this is due as restitution. This is **not** correct (*see* Conclusions, page 54).
    i. First as noted elsewhere in this report the sample size used by the Government produces an unreliable 19% confidence level vs. the standard of 51%
    ii. Second, even if it were accepted using appropriate sampling methods that all paid claims for 'unable to perform' procedures were fraudulent the correct total is $2,930,852.64 which is an error of 3.22% in the Government's calculations.
    iii. Third, as noted elsewhere the Government fails to link all of the claims associated with the procedures and CPT codes in question to the exact device that was used to perform the procedure. I have no data to conclude any amount for 'unable to perform' codes and presume that in the absence of provable data and statistically valid methods that this is zero.

14. As noted in Exhibit F - Supplemental Illustrations (PowerPoint):

    a. Of over 40,000 documents produced by the Government, a single page states that the Government interviewed a witness who stated that the Datrix 512 could not possibly perform some of the medical diagnostic procedures in question due to its frequency. FDA 510(k) filings do not confirm that this is true as other devices with the same frequency are indeed used to perform these procedures

    b. According to the American Medical Association, there are 14 steps involved in delivering care which would be used to determine the veracity or fraudulent nature of any claim. The Government methodology only sheds light onto partial information for four (4) of these fourteen (14) steps.

Respectfully,

Michael F. Arrigo

1

United States of America, Plaintiff,
v.
Michael Mirando, Defendant

Rebuttal Expert Report Regarding Loss

Prepared by Michael F. Arrigo

DATE PREPARED:
OCTOBER 9, 2017

I. Opinions

A. Health Insurance Routinely Pays Only Thirty Percent of What is Billed; Mirando's Business was in-line with Industry Averages of 30 Cents on the Dollar.

Based on a reasonable degree of certainty it is my opinion that:

1. Based on my knowledge, training, education, experience, industry practices and recent testimony, it is common knowledge that health care providers receive approximately 30 cents on the dollar of every claim they submit for payment to health insurers.

    a. This ratio is sometimes called the **payment to charge ratio** (or alternately if numerator and denominator are reversed charge to payment ratio)[2] and is a common metric used by health care providers and their billing personnel to measure their success in collecting reimbursement on health care claims.

    b. In statistics released by the U.S. Department of Health and Human Services (HHS) Centers for Medicare and Medicaid (CMS) in 2013 covering 3,337 U.S. health care providers illustrate that on average, health care providers knowingly billed 3.77 times what they were actually reimbursed.[3, 4] Calculating the payment to charge ratio based on this data yields a percentage of 27% as follows:

    CMS Data on Pay to Charge Ratio National Average

    $$\frac{\mathbf{1.00}}{\mathbf{3.77}} = \mathbf{0.265 \sim 27\%}$$

    c. For many health care providers, there is a wide difference between billed charges and the amounts that those providers expect to receive for services.[5, 6] Provider charges are based on a pre-determined price list where the charges for each service or product they may offer. Reimbursement rates, on the other hand, are the payments that providers are actually willing to accept for a specific service or product.[7, 8] As a result, only those who do not pay for hospital care via an intermediary payer (i.e., the uninsured) are actually subject to the listed charges. In practice, health care providers routinely accept reduced rates from the poor or uninsured. The cumulative result is that charges vary significantly and unless a Usual Customary and Reasonable (UCR) charge analysis is performed, charges are

not relevant in determining the amount individuals or insurers actually pay for health care services.[9]

d. In San Francisco Spine v. ClaimWorks,[10], [11] I opined that based on both my experience and the statements of SF Spine that health care providers typically receive 25% to 30% of the dollar value of every claim submitted.

e. Holter Labs billed nearly $11.5 million (including both legitimate charges and those the government all edges are fraudulent) and received $3.5 million, which is a 31% pay to charge ratio.

$$\frac{\text{total payments} \quad \mathbf{\$3,546,505.21}}{\text{total charges} \quad \mathbf{\$11,499,638.96}} = \mathbf{0.3084 \sim 31\%}$$

B. Any Intended Loss Calculation Must Therefore Presume that Health Care Providers Anticipate being Paid a Fraction of the Amount Billed in Healthcare Claims

Using Mirando's' business payment to charge ratio of 30.8% or ~ 31% for Holter Labs is a reasonable method to determine intended loss since:

1. It is in-line with industry norms of 27% to 30%
2. U.S. Government published data establishes that the government and health care providers all know that at most they expect to receive approximately 30% of what they bill, and therefore bill 3.77 times that number (nearly four times what they expect to be paid).

C. Health Insurance Denial Rates Are Five to Twenty-Five Percent; Mirando's Business Was Below Industry Norms at 11%

Kaiser Health News' Phil Galewitz September 2011. Denial rates for insurance policies purchased in the individual market—published for the first time as a result of the provisions in the Affordable Care Act— finds that insurers deny coverage at different rates depending on geographical location and for almost any reason. For instance, a review of the 20 most populous states find that "denial rates routinely exceed 20 percent and often are much higher" and seem to contradict industry claims to the contrary.[12]

> The numbers vary depending on the report. The industry average denial rate may be between five and ten percent, says the American Academy of Family Physicians (AAFP). Meanwhile, a contrasting 2011 Government Accountability Office (GAO) study maintains that up to one quarter of claims are denied.[13]

McKesson, a leading pharmaceutical supply chain company and healthcare software provider reports that medical billing denial rates range from 5-10%,[3] with better performers averaging 4%.[4] Some organizations even see denial rates on first billing as high as 15-20%[14]

The denial rate for Holter Labs is 11.2% vs. industry norms of up to 32%[15]

$$\frac{\text{total unpaid claims} \quad \$\mathbf{1,288,574.04}}{\text{total charges} \quad \$\mathbf{11,499,638.96}} = \mathbf{0.1120 \sim 11\%}$$

D. Maximizing Legitimate or Allegedly Fraudulent Claims Requires Aggressive Appeal Tactics; Appealing Denials is Complex and Costly.

I question the validity of this statement because the very nature of health care billing is complex. It is clear to me that Mr. Mirando was never properly trained in medical coding and billing and made incorrect assumptions about proper coding and billing. Medical coding is by its very nature complex and the appeals process is complex. The According to the American Health Information Management Association (AHIMA) there are five levels of complexity in the appeals process and at least five steps that must be taken to appeal a denied claim.[16] The decision to appeal can be complex, and organizations must ensure that the documentation contains solid evidence and support for their appeal. There may be cases where the internal impact of the appeal process outweighs the appeal itself. For example, organizations must determine if they want to use time and staff to argue a random denial of $100 when it could take hundreds of dollars in staff and legal resources to defend it. At times, it can be a matter of principle. Organizations may find that the decision to appeal a denial may need to be made on a case-by-case basis. [17]

For less efficient health care providers, one out of every five medical claims have to be reworked or appealed. Rework costs average $25 per claim,[18] and success rates vary from 55-98%, depending on the medical denial management team's capabilities.

E. Re-Billing is Common When Claims Are Denied and it Creates Duplicate Claims; Mirando's Duplicate Rate is Below Industry Norms

It has been standard industry practice to re-transmit claims to insurers every 30 to 60 days. [19] About a decade ago, this standard practice received significant scrutiny from the government, which questioned the intent — and the fact that automatically re-billing has the potential to inadvertently produce double (or more) payments for a single claim. [20] Automatic re-billing is more than a compliance issue, however; it tends to produce a significant number of duplicate claims.[21] Although the practice of rebilling is discouraged, it is common. [22]

A duplicate claim is one that's resubmitted for a single encounter on the same date, by the same provider, for the same beneficiary, for the same service or item. It's denied as a duplicate with error code CO18. Duplicates are one of the largest reasons for Medicare Part B claim denials, According Government Accountability Office (GAO) study it's as much as 32%. **CMS notes, however, that claims rejected as duplicates may be valid claims for payment, if the correct condition codes or modifiers are applied to demonstrate a claim isn't really a duplicate**. [23]

The duplicate claim rate for Holter Labs is 5%

$$\frac{\text{total unpaid claims} \quad \$538,515.73}{\text{total charges} \qquad \$11,499,638.96} = 0.0468 \sim 5\%$$

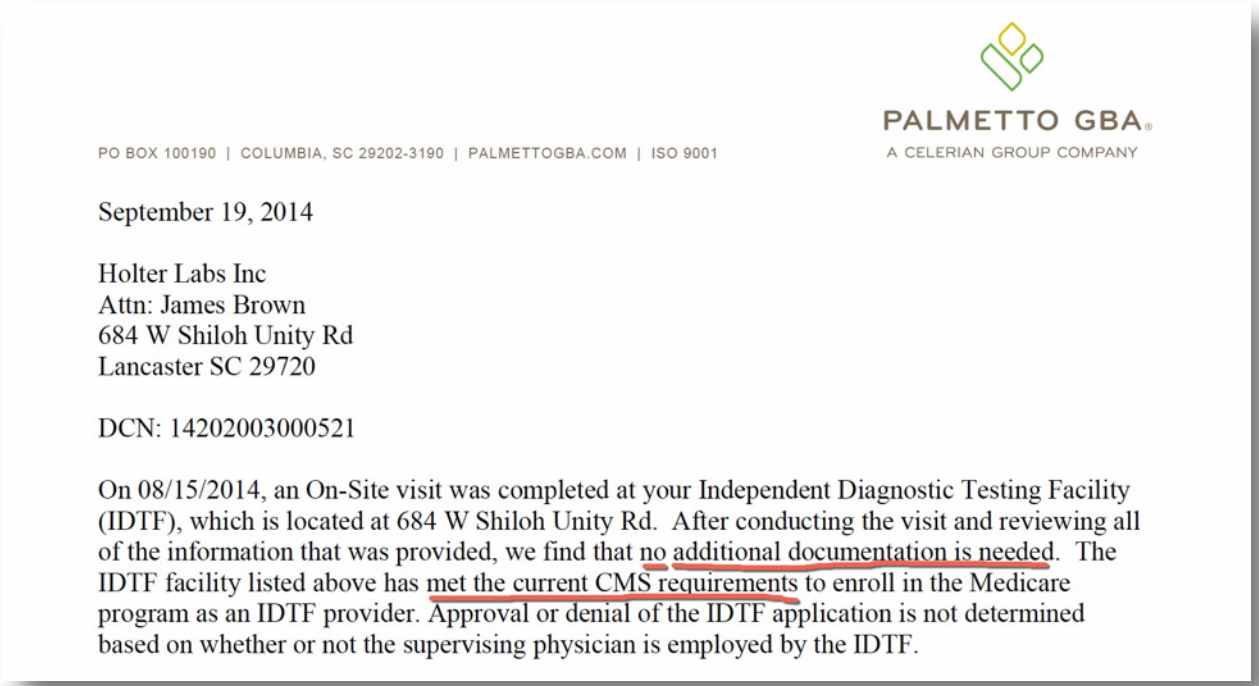
F. Providers Who Attempt to Perform Complex Medical Billing on Their Own Have Higher Denials and More Regulatory Inquiries. Mirando Was Ill-Advised to do his Own Coding and Billing.

1. The level of complexity in medical coding and billing suggests that Mirando's decision to do his own coding was neither wise nor in his best interests. Reviewing Mirando's records, denial ratios, duplicate claims ratios and other factors revealed errors on multiple levels. Using a certified coder on his staff or outsourcing billing to properly use the right CPT code, modifiers, supervisory guidelines, and claims scrubbers to find problematic claims before they were submitted would certainly have lowered Holter Lab's error rate and decreased the probability of scrutiny regarding licensure levels, supervision inquiries, and ultimately, accusations made by the Government.

2. The complexity of the coding and modifiers are very situational and require focus as well as expertise that in my opinion no one without medical training or a certification in coding should ever undertake without assistance. As a result, based on my analysis, Mirando's coding practices demonstrate a lack of coding knowledge. Using methodology discussed below, the available information suggests, based on the information available to me, a certified medical coder our outsourced billing company would have been proactive in identifying issues before they became denials or red flags for audits.

3. I am currently retained by an Independent Diagnostic Testing Facility (IDTF) that performs the same procedures as Mr. Mirando's Holter Labs performed, and I have arrived at similar conclusions when performing loss calculations for health care providers in recent retentions where there is complex data.

4. Despite the fact that Mirando had no billing expertise other than Stan Crowley's non-certified coding guidance, there were not audits of any of Holter Lab's claims. In fact, Medicare which generally has the highest denial rate and most aggressive audit and anti-fraud policies of any payor sent Holter Labs a letter in 2014 indicating that after an on-site visit on August 15, 2014 that it met CMS requirements and no further documentation was needed. See the figure below.



PALMETTO GBA
A CELERIAN GROUP COMPANY

PO BOX 100190 | COLUMBIA, SC 29202-3190 | PALMETTOGBA.COM | ISO 9001

September 19, 2014

Holter Labs Inc
Attn: James Brown
684 W Shiloh Unity Rd
Lancaster SC 29720

DCN: 14202003000521

On 08/15/2014, an On-Site visit was completed at your Independent Diagnostic Testing Facility (IDTF), which is located at 684 W Shiloh Unity Rd. After conducting the visit and reviewing all of the information that was provided, we find that no additional documentation is needed. The IDTF facility listed above has met the current CMS requirements to enroll in the Medicare program as an IDTF provider. Approval or denial of the IDTF application is not determined based on whether or not the supervising physician is employed by the IDTF.

Figure 2 - Letter from Medicare Administrative Contractor Palmetto GBA to Holter Labs - provided by counsel. Annotations added by Michael Arrigo

G. Weaknesses in the Government's Calculations Regarding Damages

The Government extrapolates from only seven (7) patients to over $7 million in billed claims and $2 million in net payments received by Holter Labs in the indictment and a smaller list of four patients in the fraud Counts in the PIR / PSR. However, when one looks at the specific claims one can argue that many if not most of the fraudulent accusations would have to be proven by much larger sample sizes. Based on an independent analysis of the Government's data and calculations and my assessment of the data produced:

1. The only way to clearly establish healthcare billing fraud or the absence of fraud is to look at the patient's medical records, what was prescribed by a physician, the coding, billing, whether the claim was paid or denied, any reasons for denial, and the payor's policies compared to industry wide generally accepted best practices. The Government does not produce a statistically valid sample of data to conclusively prove without reasonable doubt that there is over $7 million in fraudulent billing and over $2 million in fraudulently gained payments.

2. There are only $1,003.52 (one thousand and three dollars and fifty-two cents) of true duplicate claims, not $1.1 million as asserted in the PIR / PSR on page 7, paragraph 34.

Independent Analysis of Government Produced Claims Data			
Row Labels	**Count of Analysis of claim**	**Sum of BILLED AMT**	**Sum of PAID AMT**
-	**7661**	**$ 1,578,367.28**	**$ 399,250.32**
Duplicate date of service	**5107**	**$ 1,079,433.86**	**$ 369,883.36**
	5017	$ 1,059,533.96	$ 368,879.84
Duplicate Same Date of Service	90	$ 19,899.90	$ 1,003.52
Unable to perform	**17516**	**$ 7,369,392.69**	**$ 2,655,446.11**
	17516	$ 7,369,392.69	$ 2,655,446.11
Unknown	**1476**	**$ 289,313.10**	**$ 80,095.37**
	1476	$ 289,313.10	$ 80,095.37
(blank)			
Grand Total	**31760**	**$ 10,316,506.93**	**$ 3,504,675.17**

3. *Figure 3 - Independent analysis of alleged fraud by the government – uses government totals of $10.3 million, $3.5 milion but points out that true duplicate claims are only $1,003.52 from 90 claims.*

In the data above, 7,661 in total claims had no categorization, 5,017 are alleged duplicates but only ninety (90) are true duplicates with the same date of service, which may be explained as duplicate claims inquiries, eligibility checks, or duplicates but there is insufficient data to be able to know definitively. There are 17,516 claims the that match the Government's alleged 'unable to perform' category, an additional 1,476 in claims with an unknown categorization and a total of 31,760 in claims. The methods to examine these claims are detailed in the Discussion section, and **Exhibit B** – Principles and Methods and **Exhibit C** – Test Results.

H. Government Sampling Method Provides 19% Confidence Level vs. 51% Minimum Standard Certainty

1. There are alleged unable to perform claims of $7.3 million billed and $2.7 paid 'suspect' and 'impossible to perform' claims that are **not** beyond a reasonable doubt (95% to 99% certainty) or even a lower standard of 'reasonable degree of certainty' (51% probability) which must be excluded from my damages calculations.
2. The PIR / PSR states in paragraph 37 that the unable to perform payments are $3,025,329.47 and that this is due as restitution. This is **not** correct.

iv. First as noted elsewhere in this report the sample size used by the Government produces an unreliable 19% confidence level vs. the standard of 51%

v. Second, even if it were accepted using appropriate sampling methods that all paid claims for 'unable to perform' procedures were fraudulent the correct total is $2,930,852.64 which is an error of 3.22%

vi. Third, as noted elsewhere the Government fails to link all of the claims associated with the procedures and CPT codes in question to the exact device that was used to perform the procedure. I have not data to conclude any amount for 'unable to perform' codes and presume that in the absence of provable data and statistically valid methods that this is zero.

I. No Offset for Unpaid Claims in Government Loss Calculations

The government excluded in its damages calculations unpaid claims which may be legitimate (i.e. they are health care claims submitted by Holter Labs which are for non- 'suspect' CPT codes totaling $ **$1,339,180.04.**

Of a total of $10,316,506.93 in total claims in the Government's analysis here are my comments about each category:

a. Appears to be valid - The Government admits that 7,661 individual claims totaling $1,578,367.28 in billings and $399,250.32 in receipts associated with those claims appears to be valid. This is mostly, if not all associated with Holter Labs after the business was moved to Oregon and after the two former Partners of Mirando were out of the business.

b. Duplicate date of service – The Government produced data indicating that there are 5,107 claims with duplicate dates of services totaling $1,079,433.86 in billings and $369,883.36 in allegedly fraudulent gains.

vii. However as detailed herein, 'duplicates' are considered multiple bills that may be i) adjacent dates ii) different CPT codes. As the PowerPoint analysis shows, these 'duplicates' do not appear (based on the Governments small sample size) to be problematic from the perspective of the National Correct

Coding Initiative (NCCI) standard. The combinations of codes and procedures appear to be acceptable based on NCCI which is a nationally accepted standard.

viii. There are only ninety (90) claims out of 31,760 that are true duplicates for the same date of service totaling $19,889.90 in claims and a net of $1,003.52 in receipts to Holter Labs.

c. Unable to perform – the Government produced data includes 17,516 claims totaling $7,369,392.69 in claims billings and net receipts associated with those claim of $2,655,446.11. "Unable to perform" means the Government believes these services will billed but the medical device could not perform that diagnostic service. However, there is no evidence available to me as to what device was used to provide these services. This device type would not be included in the claim file, not be included in the payment to Holter and not even included in the physician's order. It would have to be determined by interviewing each physician who performed the procedure individually for 17,516 claims. To produce a statistically valid sample to even attempt to project that claims are fraudulent based on a 99% certainty with 5% error, six-hundred and forty-two claims (642) would have to be sampled to say without a reasonable doubt that these are fraudulent. The government only sampled seven (7) patients and not all of them necessarily received 'unable to perform' categories of services. Second, based on the 510(k) FDA forms, it is not necessarily 'impossible" for the device to perform these services. It has the same frequency and bandwidth as other devices certified to perform these services. (See Exhibit E).

d. Unknown – the Government data has 1,476 claims totaling $289,313 in billings and $80,095.37 in receipts considered "unknown."

15. In conclusion, the largest fraud amount that could be directly proven from the Government analysis is less than $17,282.

	Total Billed	Total Paid
Hattrup	$ 3,840.05	$ 3,540.00
Foster (Sixtos)	$ 2,685.00	$ 747.60
Bennett	$ 3,055.01	$ 1,089.01
Solmor	$ 1,115.00	$ 133.75
Total	$ 10,695.06	$ 5,510.36

Figure 4 - Independent Analysis of Government produced data – of the seven (7) patients in the indictment, four are used as the basis for sentencing and restitution projections

Even then, the methodology behind this total has inadequacies because of the error rates and because there was no audit directly linking the duplicate billing to each Counts of fraud. Even in the Governments PSR there are errors of six to 26 percent (see figure below) and concludes that the Fraud was $9,920, an error of 8%.

Government Fraud Counts vs. Arrigo Calculations

	Government				Arrigo Analysis		
	Presentencing Info. Report	No of Claims Analyzed for Each Insured	Difference	Governmen t Error Rate	Total Billed	Total Paid	Gov.: No of Claims by Analyzed by
Hattrup	$ 3,615.00	69	-$ 225.05	-6%	$ 3,840.05	$ 3,540.00	69
Foster (Sixtos)	$ 2,135.00	12	-$ 550.00	-26%	$ 2,685.00	$ 747.60	12
Bennett	$ 3,055.00	49		0%	$ 3,055.01	$ 1,089.01	49
Solmor	$ 1,115.00	7		0%	$ 1,115.00	$ 133.75	7
Total	$ 9,920.00	137	-$ 775.06	-8%	$ 10,695.06	$ 5,510.36	137
Total Claims in Data Produced by Government							**31,760**

Figure 5 - Comparison of Government Calculations in PSR v. Arrigo Analysis

16. I do not believe the Government has proven that the Datrix DR512 was the device used in all cases to do diagnostic procedures. (*See* Discussion of Gaps in the Government's Methodology to calculate damages and Exhibit E).

17. In my opinion, the Government has clearly established that the devices cannot do brain scans (EEG). There is much more to discuss this is only a quick briefing for you to determine next steps. Even if this were the case, many if not most of the claims in question in data produced by the government are for cardiac or autonomic nerve disorders. [24] See the 510k documents I am providing which do mention EKG or ECG but do not state that the device cannot be used for EEGs. There are guidelines for FDA 510k devices – we need to discuss. (*See* Discussion of Gaps in the Government's Methodology to calculate damages and Exhibit E).

18. Mr. Mirando's business appears to do autonomic testing, and the Caird software apparently can perform autonomic nerve testing (Caird software capabilities, produced by Government) and publicly available sources.[25]

19. In my opinion, the Government has not clearly established without reasonable doubt that the majority of the billings are inappropriate, other than for a small sample of seven (7) patients (*see* test results, **Exhibit C**). Based on my initial test of one patient interviewed by the FBI, the patient's physician documentation and the test report do not show any irregularities when I used a National Correct Coding Initiative (NCCI) based claims scrubber.

20. In my opinion, the Government has not clearly established without a reasonable doubt that the insurance billings are inappropriate with respect to medical necessity because no evidence of insurance denials, pended claims, or audits are provided indicating any incorrect or inappropriate coding or billing. The researcher notes, "I reviewed the Medicare billings data for these new entities – looks legitimate." [26]

J. The Government's Omission of Payment to Charge Ratio, Unreliable Sampling Methods, Overstated Intended Loss by Between $5.5 and $7.9 Million

Based on my testimony in several cases involving the Affordable Care Act, it is my understanding that for purposes of Healthcare Fraud cases, the 2010 Patient Protection and Affordable Care Act (commonly referred to as "Obamacare") changed, quite significantly, how that calculation is made. [27]

Under USSG Section 2B1.1, it is my understanding that the court must determine what the "loss" was related to any healthcare fraud offense. The question becomes, what counts as "loss." Loss can be "actual" – defined as "the reasonably foreseeable pecuniary harm that resulted from the offense;" or it can be "intended" – defined as "pecuniary harm that was intended to result from the offense." [28]

I am also aware from other loss and damages calculations where I was retained by counsel for the Relator in San Francisco that the 'foreseeable' loss in health care fraud cases, is amount billed to an

insurer, if not rebutted, however, the parties may introduce additional evidence to support arguments that the amount billed overestimates or understates the defendant's intent (*See* U.S. v Popov and U.S. v. Prakash).[29]

M. No Stated Error Rate or Sampling Methods Can be Found in Government Analysis

The Government fails to include any estimate of the error rate, margin of error, confidence level or response distribution in its statements of loss in U.S. v. Mirando. Error rates are, in my opinion absolutely essential to provide an estimate of losses. There are standard mathematical methods for calculating error rates and ensuring a reasonable sample size but these are not provided anywhere in the tens of thousands of pages produced by the Government. These methods are easy for a layperson or other expert to determine with a fundamental understanding of statistics and probability. **In my opinion, a 19% confidence level is completely unacceptable for loss calculations. Any losses extrapolated from 137 data points to project to tens of thousands of data points for sentencing or restitution cannot be relied upon.**

	Actual Government Methodology and Sample Size	Appropriate Sample Size for Statistical Validity
Population size (number of claims in Government document discovery)	31,760	31,760
Sample Size Used	**137**	**1,149**
Response distribution of 50% (each value is	50%	50%
Margin of error	1%	1%
Confidence level (a 51 percent confidence level +/- 1% margin of error yields 50% to 52% confidence level. A 19% confidence level + /- 1% margin of error yields an 18% to 20% confidence level.)	**19%**	**51%**

Figure 6 - Error Rate in Government Loss Calculations vs. Best Practices for Minimum 51% Certainty

For example, Raosoft provides a calculator that allows a low standard of confidence level such as 51%. Many online calculators will not even allow such a low level of confidence, since it is a statistically low standard and instead only provide the option to use confidence levels of 80% to

95% to 99%. However, if a layperson or other expert wishes to validate my calculations without manually performing the z-score calculations they can be checked here: http://www.raosoft.com/samplesize.html

K. The Government Methodology Leads to Unreliable Conclusions Based on Statistically Invalid Sample Sizes and Extrapolations that Overstate Intended and Actual Loss

1. The government bases its entire loss calculation and sentence in the Pre-Sentencing Report (PSR) aka Pre-Sentencing Information Report (PIR) on an in-adequate examination of 137 health care claims out of a total of 31,761 claims.
2. The Government's result in a confidence level of 19%, far below the standard that I am held to as an expert of at least 51% certainty to arrive at opinions that have a 'reasonable degree of certainty.'
3. Based on my knowledge training education (including University of California Irvine in Statistics and Economics and Stanford Medical School in biomedical informatics and statistical analysis for medicine) calculations of proper confidence levels and error rates, the Government should have analyzed the underlying documentation for a minimum of 1,149 claims but did not to do so.
4. To review my detailed analysis and underlying assumptions and my basis for these opinions, see **Discussion** section, **Exhibit B** – Principles and Methods and Test Results in **Exhibit C**).

L. The Government PSR contains Mathematical Errors of between 6% and 26%

Counts 1 to 14 of the PSR under count the amount of loss by $775.06. I point this out for two reasons:

1. My goal is to always serve as an unbiased expert who provides opinions based on the facts, no matter which part retains me. Though this under-counting is favorable to the Government I feel compelled to point it out.

2. The mathematical errors are based on an underlying flawed methodology which, while undercounting the loss based on counts 1-15 in the PSR has the effect of unreasonably over

stating intended loss by $millions, overstates the actual loss by $millions, and ignores the offset of over $1 million in unpaid claims by the named insures in the indictment.

M. Summary of Losses – 18 Level Increase for Sentencing is Not Reasonable

1. Paragraph 46 of the PIR / PSR states, "As the intended loss of approximately $8.4 million is greater than the actual loss of approximately $3 million, the approximately $8.4 million intended loss amount is used for guideline computation purposes. As USSG § 2B1.1(b)(1)(J) correlates to loss amounts between $3.5 million and $9.5 million, an 18-level increase applies." I disagree with this finding because:

    a. Government data published by CMS in 2013 states that both the government and health care providers are aware that in a survey of over 3,300 hospitals and other providers, typically one knowingly acknowledges that bills in health care claims are 3.77 times on average what they expect to be paid. [30, 31]

    b. Since it is common knowledge amount payors and providers that 3.77 (nearly four times the net paid amount) is billed, the intended loss cannot be the gross billed amount but a net amount of actual loss of $2,482,751.39. This is because when applying the 31% paid to charge ratio of Holter Labs which is commensurate with the industry standards, 31% of the billed amount is less than the actual loss. The Actual loss is slightly higher (again I disagree with the methodology and the total amounts but am stating these to illustrate) at $2,587,360.23.

    c. I am also aware from other loss and damages calculations where I was retained by counsel for the Relator in San Francisco that the 'foreseeable' loss in health care fraud cases, is the amount billed to an insurer, if not rebutted, <u>however</u>, the parties may introduce additional evidence to support arguments that the amount billed overestimates or understates the defendant's intent (*See* U.S. v Popov and U.S. v. Prakash).[32]

N. Summary of Losses Billed as Intended vs. Paid as Actual, Foreseeable

As noted in the prior section regarding summary of losses:

a. Government data published by CMS in 2013 states that both the government and health care providers are aware that in a survey of over 3,300 hospitals and other providers, typically one knowingly acknowledges that bills in health care claims are 3.77 times on average what they expect to be paid. [33, 34]

d. Since it is common knowledge amount payors and providers that 3.77 (nearly four times the net paid amount) is billed, the intended loss cannot be the gross billed amount but a net amount of actual loss of $2,482,751.39. This is because when applying the 31% paid to charge ratio of Holter Labs which is commensurate with the industry standards, 31% of the billed amount is less than the actual loss. The Actual loss is slightly higher (again I disagree with the methodology and the total amounts but am stating these to illustrate) at $2,587,360.23.

b. I am also aware from other loss and damages calculations where I was retained by counsel for the Relator in San Francisco that the 'foreseeable' loss in health care fraud cases, is amount billed to an insurer, if not rebutted, however, the parties may introduce additional evidence to support arguments that the amount billed overestimates or understates the defendant's intent (*See* U.S. v Popov and U.S. v. Prakash).[35]

Based on an analysis of billed, intended (billed times 31% and actual paid) the maximum foreseeable loss is $2,587,360.23.

H. Offset of Actual Foreseeable Loss by Unpaid Claims

My analysis (See Principles and Methods, **Exhibit B** and Test Results, **Exhibit C**) indicates:

c. There are $1,339,180.04 in unpaid claims in the data provided by the Government that should offset any calculation of fraud or restitution.

d. When this is included in the total calculations I get a negative number, meaning that the insurers potentially owe Mr. Mirando and Holter Labs funds and that there is no loss to the insurers.

e. Additional claims totaling 7% of the economic value of Holter Labs' historical claims were never produced and contain an additional offset of $95,21.04 in unpaid claims.

a. The Government's analysis is based on 31,761 claims but Holter Labs submitted over 34,000 claims based on data from Holter Labs in total.[36] Therefore, the Government excluded 7% of all claims filed by Holter Labs. This is calculated as follows: 34,000 claims minus the 31,760 claims in the Government's analysis divided by 31,760 claims equals 7%. The formula is as follows:

$$\frac{(34{,}000 - 31{,}761)}{31{,}760} = 2{,}240 \div 31{,}761 = 0.0705 \; or \sim 7\%$$

b. Using the 7% and applying it to total claims submitted by Holter in the Government discovery, I concluded that the mathematical error in summing total claims submitted by Holter was also miscalculated. Holter submitted 'gross claims' (including legitimate claims and any suspect or duplicate claims) of $11,499,638, which therefore represents 93% of all claims ever submitted by Holter Labs, or $12,365,202.15. Based on Holter Lab's denial rate and duplicate claims rate (whether presumed to be fraud or simply a re-bill to attempt to secure payment), at least 11% (factor calculated in above opinions) 11% of the claims not produced by the Government are also unpaid which would serve as an additional offset of 11% times the difference between $12,365,201.15 and $11,499,638 = $865,564 times 11% or $95,212.04

c. Therefore, the hypothetical total offset could be higher ($1,339,180.04 plus $95,21.04 which equals $1,434,392.08) but I used $1,330,180.04 in my calculations since the Government did not produce all of the data.

d. The Government did not offset any amount in its own data and calculations.

2. The government produced statistically unreliable methods to support that claims were duplicated; therefore, I subtracted those duplicate claims totaling $368,880.

I. Government drew conclusions about total value of medical procedures based on allegedly 'suspect' CPT codes, procedures - failed to link to data to prove fraud

a. without auditing the underlying claims data using a statistically valid sample to project the total number of claims that it alleges were unable to be performed
b. without confirming whether the devices used for each medical claim in question to confirm that they were fraudulent or unable to be performed,
c. by instead extrapolating from seven to fifteen patient files to draw this conclusion for thousands of claims and $millions in alleged fraud.
d. by relying on a single witness who stated that the device was 'unable to perform' the services in question when FDA 510(k) filings demonstrate that devices with the same frequency are used for exactly the same types of procedures in question in this case.

Therefore, $2,574,940 were also subtracted.

3. The Government presented evidence for counts of fraud totaling $17,282 in the indictment and $9,920 in the PIR / PSR which is mathematically incorrect and based on patients who served as witnesses and their physicians, though in some cases medical records documenting the statements of these witnesses were not performed and only the recollection of the witnesses regarding services received several years in the past was relied upon.

a. Based on my knowledge training education and experience, patients do not often remember what treatments they received a few weeks ago, let alone months or years ago
b. similarly, physicians usually need to rely on their SOAP notes to recall what services were or were not rendered.

O. Findings of Total Loss

The $2,587,360.23 minus $1,339.180.04 minus $538,515.73 minus $2,574,940 plus the accurate fraud counts mathematical total of $10,695.06 equals a negative number of ($1,854,580.95) which means that subject to further audits, the payors (health insurance firms) in this case may owe Holter Labs for unpaid claims.

	Billed	Intended Loss	Paid (Actual Loss)	Total
Suspect + Dup	$8,008,875.45	$2,482,751.39	$ 2,587,360.23	$ 2,587,360.23
Less : Unpaid			$ 1,339,180.04	$ 1,339,180.04
	Subtotal - Suspect + Duplicates Less Offset			**$ 1,248,180.19**
Less: unproven duplicates				$ 538,515.73
	Subtotal - Above Less Unproven Duplicates			**$ 709,664.46**
Less: unproven unable to perform				$ 2,574,940.47
	Subtotal - Above Less Unproven Unable to Perform			**$ (1,865,276.01)**
Add: accurate mathematical total for Counts 1-15				$ 10,695.06
	Negative number means payors owe Holter Labs			**$ (1,854,580.95)**

Figure 7 - Summary of Calculations, with Mathematical Corrections by Arrigo

In my opinion net damages are zero (mathematically a negative number which may indicate payors owe money for unpaid claims). Though in my opinion the Government methodology could have been stronger, I have left the amounts of $10,695.06 (the correct mathematical total) my calculations.

II. Expert Qualifications, Publications, Testimony, Compensation

A. Education

I earned my Bachelor of Science in Business Administration from the University of Southern California, Marshall School of Business, in 1981. I studied at Stanford Medical School in Biomedical Informatics and am currently studying at Harvard Law School in Bioethics.

B. Experience

I previously worked for various Silicon Valley companies, including Oracle, Hewlett Packard, Symantec, Borland and Intel, with roles ranging from analyst to Product Manager, Vice President of Marketing and Sales, Corporate Development and Management Consultant. I was also previously the Senior Vice President of eCommerce for Fidelity and First American's CoreLogic business.

I am currently the Managing Partner of No World Borders. In this role, I consult with and advise healthcare organizations and investors regarding healthcare-related regulations, including medical

record and billing documentation, the International Classification of Diseases version 10 from the World Health Organization (WHO) (ICD-10) which is the new coding standard as of October 1, 2015 in support of Section 1886(d) of the Social Security Act and Title 42: Public Health Part 412—Prospective Payment Systems for Inpatient Hospital Services, Current Procedural Terminology (CPT) coding, compliance programs, business damages, Medicare and Medicaid insurance fraud, Workers Compensation medical bills and fraud under State Labor codes, Usual, Customary and Reasonable (UCR) medical charges (Criteria for determining reasonable charges 45 CFR §405.502), the Health Insurance Portability and Accountability Act (HIPAA Privacy Rule 45 CFR Part 160 and Subparts A and E of §164, and HIPAA Security Rule 45 CFR §160 and Subparts A and C of §164), the Meaningful Use provisions of the American Recovery and Reinvestment Act of 2009 (ARRA) specifically the Health Information Technology for Economic and Clinical Health including security risk analysis (HITECH Act 45 CFR §164.308(a)(1)), Meaningful Use Provisions for Electronic Health Record certification criteria (including § 170.304-§ 170.314), Standards for the Electronic Health Record Technology Incentive Program (physician and hospital HITECH Act Stimulus funds) 42 CFR Part 495 Subpart B—Requirements Specific to the Medicare Program and Subpart D—Requirements Specific to the Medicaid Program, the Confidentiality of Medical Information Act ("CMIA") California Civil Code section 56, *et seq*. In addition to these regulations, I also consult with and advise healthcare organizations regarding health care claims reimbursement, coverage determination provisions of the Patient Protection and Affordable Care Act of 2010 including Prohibition of Preexisting Condition Exclusions (45 CFR § 147.108), Medicare Expansion and Health Insurance Exchanges, the Office of the Inspector General (OIG) self-disclosure, and HIPAA data breach response and remediation. A copy of my Curriculum Vitae and listing of publications is attached hereto as **Exhibit A**.

In my role as Managing Partner of No World Borders and based on my education and experience, I have knowledge regarding the industry standards and regulations, guidelines and best practices in private insurance, Medicare, Medicaid, Workers Compensation, and other payors under fee for service, capitated, and risk based payment methods under Medicare Part C and the Affordable Care Act. By virtue of my training, education, knowledge and experience, I can fairly evaluate the damages in this case.

C. Specialized Knowledge, Publications and Prior Testimony

My relevant experience includes management of a firm and a team of professionals that advise health plans, hospitals, and health IT technology firms and health care investors. Details are

provided in my Curriculum Vitae, **Exhibit A**. My litigation consulting experience includes recent retention by the U.S. Department of Justice in a False Claims Act case that resulted in a $155 million settlement for the U.S. where my responsibilities included in part to perform loss calculations (*see DOJ Press Release* "Electronic Health Records Vendor to Pay $155 Million to Settle False Claims Act Allegations" May 31, 2017*)*. Within the past two years, I also served in a *qui tam* case involving a Federally Qualified Health Center (FQHC) and its executives as Defendants. FQHCs are one of the models that the U.S. Department of Health and Human Services uses to provide care for underserved populations, and like Disproportionate Share Hospitals, both types of entities receive special incentives from the government to do so.

I have performed damages and loss calculations four times in 2017 in cases involving fraud, medical coding and billing litigation (two in state court, two in federal court and one scheduled in federal court in November 2017). I have been certified as an expert in 2017 by a Judge [37] in one of these disputes and my testimony has never been excluded. I have provided opinions on the record in 35 cases to date. I am currently retained by the U.S. Department of Justice to evaluate potential losses regarding alleged fraud by a health care provider. I have studied at Stanford Medical School in Biomedical informatics under Dr. Kristin Sainani PhD regarding statistics for Medicine and statistics and economics at the University of California, Irvine. I have performed analysis and provided opinions on the value of health care claims, loss and damages totaling over $4 billion to date between my role as leader of a management consulting firm in the health care industry and my litigation consulting experience.

Publications

A list of all publications I have authored in the previous 10 years is included in my Curriculum Vitae, **Exhibit A,** including prior publications regarding medical coding and the economic value of health care claims processing using such codes.

Prior Testimony

A list of all other cases in which, during the previous 4 years, I have testified as an expert at trial or by deposition is provided in **Exhibit G** **(Federal Rule 26 Required Disclosure of Prior Testimony over the Past Four Years)**.

Testimony has Never Been Excluded

Exhibit G contains a list of over 35 cases where I have provided opinions on the record. My testimony has never been excluded. I have survived a motion to Exclude under the Daubert standard in Federal Court (confidential / sealed case before the Federal Trade Commission), a recent motion to exclude in Dallas Texas where my opinions were being offered with respect to medical coding, medical billing and the economic value of historical claims as well as future value of healthcare under the Affordable Care Act. Judge Ambler recently certified me as an expert in San Jose, CA in October 2017 where my testimony was provided under oath in a case involving medical coding, medical billing and damages / loss calculations.[38]

D. Compensation

Between January 27, 2017 and the date of this report, I have spent 124.75 hours on this matter. My billing rate is $600 per hour for expert analysis, $750 per hour for appearance at trial and depositions, and $300 per hour for travel. To date, I have been paid $69,450 and am still owed $5,400.

III. Summary of Facts and Data Considered

A. Scope of Discovery Provided by the Government

Over 40 spreadsheets and 40,000 pages of data was produced by the Government and provided to me by retaining counsel. These documents are itemized in Exhibit D, Section A – Provided by Counsel.

B. Documents independently accessed and cited.

In addition, I independently accessed over 50 documents which are listed in the end notes as Exhibit D, Section B – Documents independently accessed.

C. Mirando was not trained as biller and coder by Nationally Credentialed Organizations

Mr. Mirando was trained by his former business partners, not by certified billing trainers. The American Academy of Professional Coders (AAPC), American Health Information Management Association (AHIMA) and the North American Medical Auditing Society (NAMAS) which provides licensed training from AAPC are examples of those organizations.

D. Mirando was enticed to start a company and trained in billing practices by an unemployed whistle blower who was being sued for improper use and billing of medical devices.

Based on documents provided to me, Mr. Mirando was 26 years old and trusted an older partner Stanton Crowley. Once their relationship dissolved, Mr. Mirando prevailed in a law suit against Crowley. In April of 2015, Crowley filed for bankruptcy after Mirando's law firm filed a cross complaint against him. When he failed to answer the cross complaint, the superior court judge issued a default judgment against Crowley. Crowley filed for bankruptcy protection a day before his second debtor exam. He stated on record that he filed for bankruptcy in order to avoid having to pay Mirando.

E. The Centers for Medicare and Medicaid Stated Holter Labs Met All Requirements

As noted in the opinions section and in the letter provided as an exhibit from Palmetto GBA, a Medicare Administrative Contractor, sent Mirando's company Holter Labs a letter in 2014 stating that it met all requirements to be a healthcare contractor that submits claims for services provided to Medicare insureds.

F. Holter Lab's Denial Rate, Duplicate Clams Rates, and Payment to Charge Ratio vs. Industry Metrics

As noted in the Opinions section, I compared industry averages and ratios from published sources including the U.S. Government with those found in Holter Lab's business as one component of my methodology to determine whether the Government accurately and reasonable represented losses.

G. FDA Data Regarding Datrix 512 Frequencies and FDA 510(k) for Similar Devices

I reviewed the frequency and capabilities of the Datrix 512 device in comparison to FDA published data for similar devices and concluded that the Datrix device operates at the same frequency as other devices approved by the FDA for a broad range of medical diagnostic procedures. This data is in direct conflict with the testimony of a single Government witness regarding Datrix frequencies and capabilities to perform cardio diagnostic vs. neuro diagnostic procedures. I note in my CV that I am currently retained by another IDTF to serve as an ongoing advisor to ensure regulatory

compliance and have served as management consultant to Abbott Laboratories in their FDA Compliance in the past.

H. Industry Standard Definitions of Duplicate Claim, Whether Those Claims are Payable.

As noted in this report, CMS published guidance acknowledges that duplicate claims may exist for good reason and may be payable and are not universally considered fraud without further examination.

I. Prior Decisions in the 9th Circuit that Indicate Intended Loss, Foreseeable Loss May be Based on Factors Such as Payment to Charge Ratio

As noted in my Opinions I am familiar from other litigation consulting work with data from retaining counsel where foreseeable loss includes an allowance for the amount billed being much larger than what any provider anticipates being paid (*See CMS published data quote in Opinions section that providers knowingly bill 3.77 times what they expect to be paid).*

See U.S. Court of Appeals, 9th Circuit, Opinion February 11, 2014 http://cdn.ca9.uscourts.gov/datastore/opinions/2014/02/11/12-10045.pdf

IV. Discussion

A. Gaps in the Government's Sampling Methodology for Damages Calculations

Unreliable Sampling Methodology and Extrapolation

1. The Government used a limited set of seven (7) patients out of over 31,761 billing and claims that produces unreliable extrapolations and billing amounts of alleged fraud:

    a) There appears to be evidence that services were provided that and no documentation is provided as to whether they were requested by a clinician or not but only for selected components of the billings for seven (7) patients out of 31,761 claims. To confirm that there is truly fraudulent intent requires that the service requested by the clinician and the intent of the clinician in ordering those tests is matched to the service provided by Holter Labs LLC using a statistically valid sample size.

b) There is evidence that multiple service encounters for the same type of service were provided in relatively short time frame but only for selected components of the billings for seven (7) patients out of 31,751 claims. To confirm that there is truly fraudulent intent requires that the service requested by the clinician and the intent of the clinician in ordering those tests is matched to the service provided by Holter Labs LLC using a statistically valid sample size.

B. Failure to Link of Claims to Supporting Documentation and Physician's Records

1. The calculation of the amount would require additional linkage of provider ordering documentation and billing linked to the relevant Holter Lab LLC billing for claims in question as to billing for services not ordered or for excessive service billing unsupported by new service requests.

2. Proving that services were provided when not ordered will require more <u>complete</u> data for claims and documentation from both the client and Holter Labs LLC. To provide a statistically valid projection of fraud with a 99% confidence level and a margin of error of 5%:
   A. The complete data would need to be analyzed by in a random sample of at least 652 of the 31,761 claims, or a sample of 2.05% (z score of 1.96 or nearly two standard deviations from the mean) [39] which is sometimes called a 'normal' distribution of data.

$$Sample\ Size = \frac{\frac{z^2 \times p(1-p)}{e^2}}{1+\left(\frac{z^2 \times p(1-p)}{e^2 N}\right)}$$

Figure 8 - Population size = N, margin of error = e, z score = z.

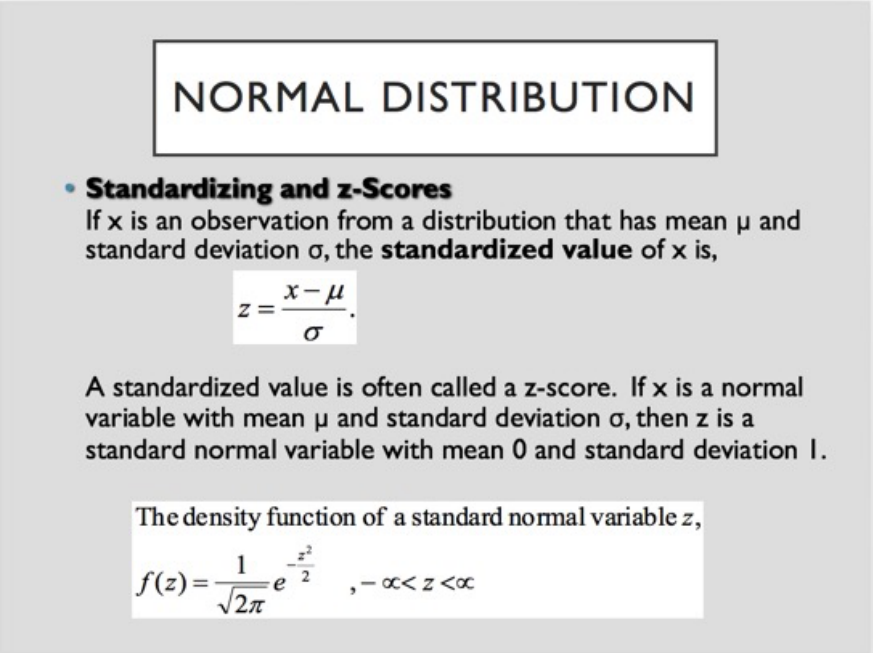


Figure 9 - Standardizing z scores for normal distribution. (See Cite)[40]

Limited Degree of Certainty and High Margin of Error in Government Methods

3. Similarly, to conclude with 95% certainty and a 5% margin of error that specific claims such as the 3,171 claims denoted with CPT code **93025** are fraudulent, at least 343 claims would have to be completely analyzed.
4. I also calculated the 'reasonable degree of certainty' or what in my opinion is generally considered to be a 51% certainty with low error rate and concluded that the Government should have analyzed at least 1,149 records. A complete analysis would require determining whether the procedure was performed as described "Microvolt T-wave alternans testing is performed to assess patients who are at risk for sudden cardiac arrest due to previous heart attack, heart failure, left ventricular dysfunction, unexplained syncope, or family history of sudden cardiac arrest. A set of 14 electrodes are distributed on the torso and attached to the ECG machine. Seven are standard electrodes while the other seven are special microvolt T-wave alternans sensors. ECG recordings are obtained while the patient walks on a treadmill while slowly increasing treadmill speed to increase the heart rate gradually. Alternatively, heart rate may be increased pharmacologically or using a pacer. The special microvolt T-wave alternans sensors are able to detect extremely small changes in the T-wave portion of the ECG that are not visible to the naked eye on the ECG recording. The test continues until T-wave changes are detected or until the patient achieves the desired heart rate without evidence of T-wave changes. The physician reviews the ECG and provides an interpretation of findings with a written report.

including viewing the patient chart, the physician's order, the actual service provided, evidence of what device was used which is not contained in the insurance claim, the insurance claim submitted, the amount paid, and whether the insurance company denied the claim, audited the records or provided a reason for not paying the claim to determine whether it is true that $1,106,777.76 was fraudulently billed and $314,153.63 was fraudulently received.

- According to the information made available to me, Government data made available to me by counsel, payments were made by the following payors, each of which would have to be verified:
    - Aetna
    - Anthem
    - BCBS of Alabama
    - BCBS of Florida
    - BCBS of Minnesota
    - BCBS of New Jersey
    - BCBS of Rhode Island
    - BCBS of South Carolina
    - Cigna
    - Emblem Health
    - GEHA
    - Healthfirst
    - Humana
    - Independence Blue Cross
    - Independent Health
    - Premera
    - Tricare
    - United Health Group
    - XL Health

5. Similarly, to conclude with 95% certainty and a 5% margin of error that 4,967 claims denoted with CPT code **93226** are fraudulent, at least 357 claims would have to be completely analyzed. A complete analysis would include confirming whether these steps were completed:

- Electrocardiographic (ECG) rhythm-derived data is gathered for up to 48 hours of monitoring as the patient goes about regular daily activity while wearing an external ECG recording device, also called a Holter monitor. Electrodes or leads are placed on the patient's chest, and the patient is instructed on the use of the monitor. The recording device makes continuous, original ECG wave recordings for a 12 to 48-hour period. The recordings are captured on magnetic tape or digitized medium to be reviewed later. At the end of the recording period, the patient returns to the office with the device. Stored data derived from the continuous recordings of the electrical activity of the heart include heart rhythm and rate, ST analysis, variability in heart rate and T-wave alternans. Visual superimposition scanning is done to give a 'page review' of the entire recording, identifying different ECG waveforms with selective samples of rhythm strips. A report is made after analysis of the scanning, and the physician or other qualified health care professional reviews and interprets the data for heart arrhythmias. connection, recording, and disconnection.

- Each claim would need to be verified including viewing the patient chart, the physician’s order, the actual service provided, evidence of what device was used (and since this is an alleged duplicate claim whether the claim was duplicated for fraud, duplicated as an additional request for payment, duplicated because the date is in close proximity to another date of service for legitimate reasons or fraudulent reasons) which is not contained in the insurance claim, the insurance claim submitted, the amount paid, and whether the insurance company denied the claim, audited the records or provided a reason for not paying the claim to determine whether it is true that $297,808.86 was fraudulently billed and $90,669.54 was fraudulently received. As noted in the detailed Methodology and Findings / Test Results sections of this report, the Government produced data indicating that there are 5,107 claims with duplicate dates of services totaling $1,079,433.86 in billings and $369,883.36 in allegedly fraudulent gains. However as detailed herein, ‘duplicates’ are considered multiple bills that may be i) adjacent dates ii) different CPT codes. As the PowerPoint analysis shows, these ‘duplicates’ do not appear (based on the Governments small sample size) to be problematic from the perspective of the National Correct Coding Initiative

(NCCI) standard. The combinations of codes and procedures appear to be acceptable based on NCCI which is a nationally accepted standard. **There are only ninety (90) claims out of 31,760 that are true duplicates for the same date of service totaling $19,889.90 in claims and a net of $1,003.52 in receipts to Holter Labs**.

- According to the information made available to me, Government data made available to me by counsel, payments were made by the following payors, each of which would have to be verified:
  - Aetna
  - Anthem
  - BCBS of Alabama
  - BCBS of Florida
  - BCBS of Minnesota
  - BCBS of New Jersey
  - BCBS of Rhode Island
  - BCBS of South Carolina
  - Cigna
  - Emblem Health
  - GEHA
  - Healthfirst
  - Humana
  - Independence Blue Cross
  - Independent Health
  - Premera
  - Tricare
  - United Health Group
  - XL Health

6. In my opinion, if and only if it is determined using methods above including a statistically valid sample size that it was not possible for Holter Labs to provide the services billed consistent with the standard of practice for these studies, each of those service claims could be considered

fraudulent. In that case, the calculation of the amount of fraudulent billing could be based on billed claims with those service codes.

7. I am aware that experts are often held to a much lower standard, "reasonable degree of certainty" which I understand to mean more likely than not or in statistical terms 51% confidence level.

Even if Lower Standard of Reasonable Degree of Certainty is Used, Government Sampling is Unreliable

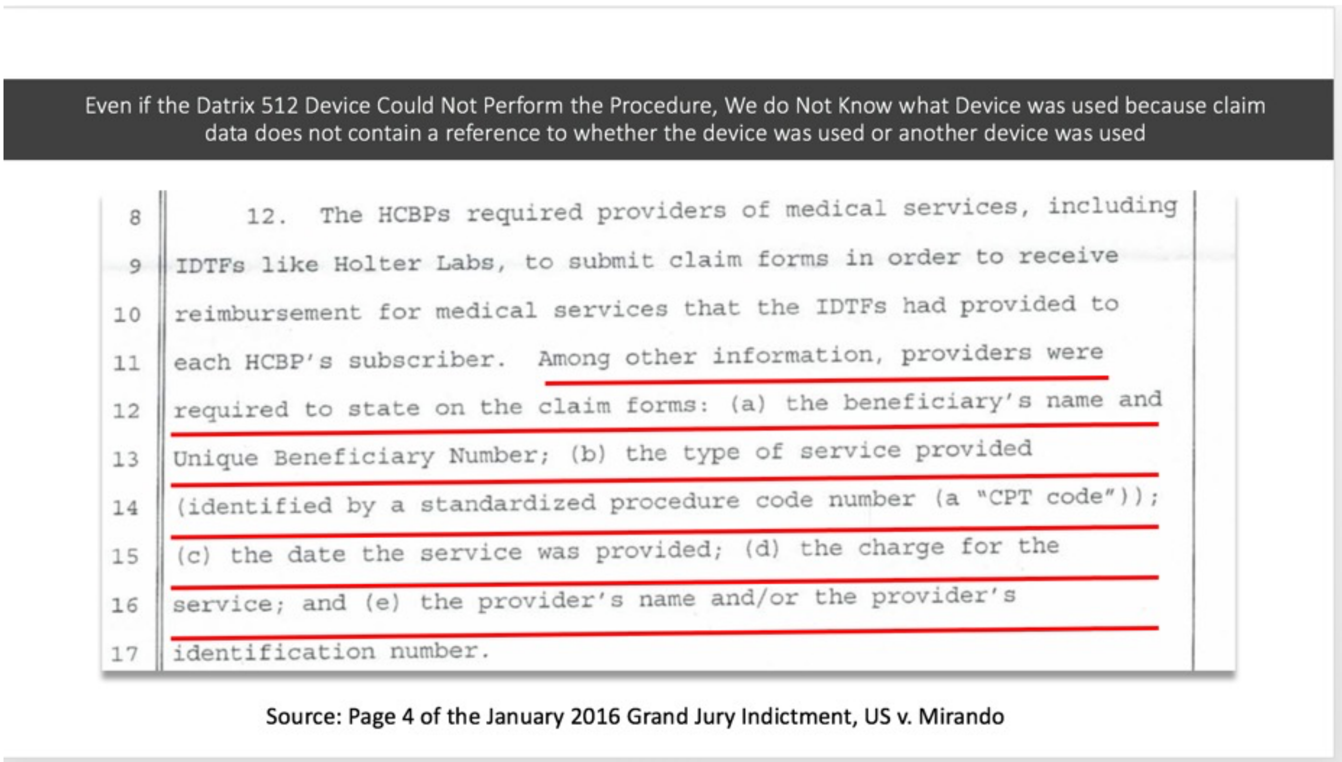
8. Even at the 'reasonable degree of certainty' level of confidence for damages calculations, and a population of 31,761 claims, a random sample of 1,201records (meaning BOTH the patient record and physicians order AND the associated claim(s)) must be reviewed.

9. I calculated the random sample size of 1,201 by using a 52% confidence level with a 1% margin of error (52% minus 1% = 51%). Again, this can be checked using the Z score calculations above. A lay person can easily check this and my calculations using a number of online calculators.[41] This illustrated in the figure below. Population is entered totaling 31,761 and a confidence level of 52% since a 1% error sometimes notated as (+/-) could result in 53% or 51% net confidence level. Next a response distribution of 50% is used.[42]

Data is Unavailable to Prove that "Unable to Perform" and Suspect Codes are Damages

10. Although experts in damages calculation work may state opinions, to the best of my knowledge, at the 'reasonable degree of certainty' level, it seems impossible to be 51% certain of a total damage amount without being 99% certain that the underlying data is 'suspect,' 'unable to perform,' or 'impossible to perform' or 'fraudulent' as the Government alleges. Much of the Government's presumption that certain procedures fall in the 'suspect,' 'impossible' or 'unable to perform' category are based on the statements that a specific Holter device could not perform a certain Neurodiagnostics (EEG) or cardio diagnostic (ECG) procedures. (*See* Exhibit E for a discussion and diagrams based on FDA form filings for medical devices and notices of intent to market (510(k)) which directly contradict these statements according to the official FDA filings. In my opinion, the FDA data does indicate that it is 'possible' based on the frequency data in the filings. Even if this possibility is dismissed and one assumes that the Datrix 512 device cannot perform a procedure, another device could have performed the procedure. I saw no facts in this case that conclusively show

that ONLY the Datrix 512 was used and that no other device was ever used. Therefore, in my opinion, to prove that a claim was filed for reimbursement with an insurance company where a specific device was used, a physical audit of every single physician's office for the claim in question would be required again pointing to the Government's lack of data and extremely low and unreliable sample size. This is because the health care claim itself does not contain any data that provides without a reasonable doubt that the Datrix 512 device was used instead of another device. Even at the lower standard of 'reasonable degree of certainty' one is again confronted with the statistical mandate to review over one thousand claims including the underlying data that supports or does not support its viability. Even in the Government's indictment, they point out that the DEVICE used in a medical procedure in the Holter Labs business is not captured in the claims data.



Even if the Datrix 512 Device Could Not Perform the Procedure, We do Not Know what Device was used because claim data does not contain a reference to whether the device was used or another device was used

12. The HCBPs required providers of medical services, including IDTFs like Holter Labs, to submit claim forms in order to receive reimbursement for medical services that the IDTFs had provided to each HCBP's subscriber. Among other information, providers were required to state on the claim forms: (a) the beneficiary's name and Unique Beneficiary Number; (b) the type of service provided (identified by a standardized procedure code number (a "CPT code")); (c) the date the service was provided; (d) the charge for the service; and (e) the provider's name and/or the provider's identification number.

Source: Page 4 of the January 2016 Grand Jury Indictment, US v. Mirando

Figure 10 - Grand Jury Indictment Annotation from Arrigo Exhibit E of this report has no linkage to the device used

11. Therefore, my opinion the Government's limited set of seven (7) patients out of over 31,761 billing and claims that produces unreliable extrapolations and billing amounts of alleged fraud for damages calculations.

Unbiased Method to Calculate Damages Must Consider all Possible Outcomes – Favorable and Unfavorable

12. In my opinion, a reliable method to calculate damages must, upon concluding without a reasonable doubt that Holter Labs submitted fraudulent claims, perform a calculation of damages or loss to insurers that must include:
    - Total loss alleged by Government
    - MINUS The sum of all claims not paid by the insurers (representing the possible 'loss' to Holter Labs
    - MINUS the value of those claims for 'suspect' or 'impossible to perform' claims that are unproven to be fraudulent.
    - MINUS duplicate claims.

Determining Medical necessity as a basis for paying or denying insurance claims

Federal guidelines and statutes and payor policies are used as factors in determining whether a medical procedure is medically necessary but the final determination is usually made by examining a patient's chart as documented by a physician.

Federal Government Guidelines

The Medicaid Act does not define the term "medical necessity." Over the years, recipients have relied on regulatory and decisional principles to define the scope of coverage. [43] According to the U.S. Government's Medicare.gov official U.S. Government site for Medicare, "Medicare **Part B covers 2 types of services: a) Medically necessary services:** Services or supplies that are needed to diagnose or treat your medical condition and that meet accepted standards of medical practice, and b) **Preventive services:** Health care to prevent illness (like the flu) or detect it at an early stage, when treatment is most likely to work best."

Statutes and best practice guidelines include:

CMS Coverage Policy - Title XVIII of the Social Security Act, Section 1862(a)(1)(A) states that no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury.

Title XVIII of the Social Security Act, Section 1862(a)(7). This section excludes routine physical

examinations.

Title XVIII of the Social Security Act, Section 1833(e) states that no payment shall be made to any provider for any claim that lacks the necessary information to process the claim.

CMS Manual System, Pub 100-02, *Medicare Benefit Policy Manual*, Chapter 15, Sections 60 and 80

CMS Manual System, Pub. 100-03, *Medicare National Coverage Determinations Manual*, Chapter 1, Section 240.4

CMS Manual System, Pub 100-04, *Medicare Claims Processing Manual*, Chapter 1, Sections 10 and 30.2 and Chapter 35

CMS Manual System, Pub. 100-08, *Medicare Program Integrity Manual*, Chapter 3, Section 3.4.1.2, Chapter 10, Chapter 13, Section 13.5.142

Code of Federal Regulations, 410.32 and 410.33

Payor Policies for Specific Types of Diagnostic Facilities and Procedures

Medicare, Private Payors, Independent Diagnostic Testing Facilities (IDTFs)

- Medicare will cover diagnostic tests performed by an IDTF when the procedures are medically necessary and the criteria in this LCD are met. The procedures in this document are also subject to applicable National and Local Coverage Determinations (LCDs).[44]
- **IDTFs are required to report the exact CPT/HCPCS codes/procedures they intend to perform when enrolling with the CMS-855B form**. If an IDTF which is already enrolled wants to perform additional CPT or HCPCS code tests that were not originally specified on its CMS-855B and that are for procedure types and supervision levels similar to its previously allowed codes, the contractor shall have the IDTF amend its CMS-855B to add the additional codes and equipment listing. A new site visit is not required. However, if the enrolled IDTF will be performing CPT or HCPCS codes for different types of procedures, or with different supervision levels, a new site visit is required. Claims submitted with

procedure codes not reported on the CMS-855B form and reviewed by the contractor will be denied.

Physician Documentation Trumps Payor Policy and Government Guidelines

Case law supports the idea that the ultimate test of whether a medical diagnostic procedure is 'medically necessary' is the patient's physician. Without knowing the physician's opinion which is documented in **progress notes** and the referral or primary care physician's **order** one cannot truly know if a procedure is medically necessary.

Even when controversial topics are challenged in court, based on my knowledge training education and experience, the physician's decision is key. Case law has also indicated that the patient's treatment and the medical necessity of that treatment is best determined by a physician. In my work as an expert, retaining attorneys have sometimes cited case law in their instructions to me (*see Pinneke v. Pressier*). [45]

Senate Report No. 404, 89th Congress, 1st session, U.S. Code Cong. & Admin. News 1965, p. 1986, states in part:

> "3(a) Conditions and limitations on payment for services.
>
> (1) Physicians' role
>
> The committee's bill provides that the physician is to be the key figure in determining utilization of health services and provides that it is a physician who is to decide upon admission to a hospital, order tests, drugs and treatments, and determine the length of stay. For this reason, the bill would require that payment could be made only if a physician certifies to the medical necessity of the services furnished."

Medicare, Private Payors, ECG or EKG

Payors such as Medicare and Private Payors may make specific requirements for Coverage Determination and Medical Necessity Determinations. Here is an example:[46]

1. Long-Term ECG Monitoring is defined as a diagnostic procedure, which can provide continuous recording capabilities of ECG activities of the patient's heart while the patient is engaged in daily activities. These can include continuous, patient-activated or patient-

demand monitoring. The purpose of these tests is to provide information about rhythm disturbances and waveform abnormalities and to note the frequency of their occurrence.

2. List the appropriate procedure code.

   a. If billing for 48 hours for codes 93224-93237, indicate this by placing each date of service on a separate line with a 1 in the units box (e.g., 010).

   b. When billing for a service of greater than 48 hours and less than 30 days, use the appropriate 30-day monitoring code with the -52 modifier, to indicate a reduced service. The documentation in the progress notes must reflect medical necessity for the service. The fee billed for the service must be appropriately reduced to reflect the time the patient required the service.

   c. List the ICD-9 code(s) (or after 10/1/15 ICD-10 code(s)) indicating the reason for the test.

   d. The physician ordering the test must be identified on the claim form in Boxes 17 and 17a with his/her UPIN number. For EMC, NSF fields FB1 - 10, 11, 12 (name) and FB1 - 13 (UPIN #) or ANSI - 837 NM1 - 03, 04, 05 (name) and NM1 - 09 (UPIN #).

   e. The physician interpreting the test must be identified on the claim form with his/her sequence number in Box 24K. For EMC, use NSF format field FA0 - 23, or ANSI - 837 or NM1 - 09 (loop 2310).

   f. The codes describing technical work may be billed by an independent physiological laboratory if they meet all requirements listed in the code descriptions and coverage requirements. They may bill the total component only if the physician interpreting the test is employed by the laboratory and is not billing for the interpretation separately. The physician's name and address must be on record with our MPCU department. A letter should be sent by the physician assigning all monies collected by the laboratory for the professional codes to the billing laboratory. If a letter is not

on file, professional services billed by the physiological laboratories will be denied.

g. The physician may bill the technical and professional codes if all the criteria listed are met.

h. Site-of-service reductions apply to these codes, i.e., if the technical component is performed in the out-patient setting, it is considered a Part A service.

i. Do not use the "TC" or "26" modifier with these codes.

j. Either the patient-activated monitor <u>or</u> the 24-hour monitor will be covered (not both)." [47]

Medicare, Private Payors, EEG

Medicare and Private Payors typically itemize specific CPT procedure codes that are permissible to bill for EEGs:

95812 - Electroencephalogram (EEG) extended monitoring; 41-60 minutes -average fee payment- $350 - $360

95813 - Electroencephalogram (EEG) extended monitoring; greater than 1 hour

95816 - Electroencephalogram (EEG); including recording awake and drowsy

95819 - Electroencephalogram (EEG); including recording awake and asleep

95822 - Electroencephalogram (EEG); recording in coma or sleep only

95827 - Electroencephalogram (EEG); all night recording

95950 - Monitoring for identification and lateralization of cerebral seizure focus, electroencephalographic (e.g., 8 channel EEG) recording and interpretation, each 24 hours

95951 - Monitoring for localization of cerebral seizure focus by cable or radio, 16 or more channel telemetry, combined electroencephalographic (EEG) and video recording and interpretation (e.g., for presurgical localization), each 24 hours

95953 - Monitoring for localization of cerebral seizure focus by computerized portable 16 or more channel EEG, electroencephalographic (EEG) recording and interpretation, each 24 hours, unattended

Diagnosis Codes that Support Medical Necessity

Payors typically list those diagnosis which support whether a treatment is medically necessary. However, again the Government's policy defers to the physician to decide: [48]

> "ICD-10-CM Codes that support Medical Necessity:
> It is the provider's responsibility to select codes carried out to the highest level of specificity and selected from the ICD-10-CM code book appropriate to the year in which the service is rendered for the claim(s) submitted."

National Coverage Determinations and Local Coverage Determinations

National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs) are used to determine when the procedures above described by CPT code will be paid.

Clinical Documentation as Basis for Diagnosis

NCDs and LCDs rely principally on specific patient conditions which must be documented by the physician to support a specific diagnosis. The presence of a diagnosis is the key indicator of whether a procedure is medically necessary. For example,

Prior Tests to Establish Medical Necessity for Additional Tests or Procedures

Medicare and other payors may require that prior conditions be met before allowing or covering payment for an additional procedure. For example, "Ambulatory EEG should always be preceded

by a routine EEG. A routine EEG is described by CPT codes 95812, 95813, 95816, 95819, 95822 or 95827 and refers to a routine EEG recording of less than a 24-hour continuous duration."[49]

Payor Denials

If a payor (whether a government payor such as Medicare or Medicaid or private insurer such as Aetna, Cigna, Blue Cross or others) questions whether a procedure is medically necessary they have several tools at their disposal to examine a healthcare claim:

1. Pending claims and requesting more information, in which case the provider may be required to provide substantiation for medical necessity in the form of the patient's chart (including progress notes). Usually the payor will provide an explanation in the form of **reason codes** when pending a claim to provide specific information on what data they feel is missing. If the provider supplies the missing information when appealing the decision, the claim may be paid.

2. Denial of a claim, which can be appealed by a health care provider. Usually the payor will provide an explanation in the form of **reason codes** when pending a claim to provide specific information on what data they feel is missing. If the provider supplies the missing information when appealing the decision, the claim may be paid.
3. Audits – if the payor determines in its opinion that there is a pattern of pended or denied claims or unusual patterns of claims such as multiple claims on the same date of service (DOS) for the same patient it may request an audit of the healthcare provider's records. If the provider supplies the missing information in an audit, the current claims in question and any future similar claims are more likely to be paid.

Incomplete or Inconclusive Analysis by FBI

Failure to Prove Lack of Medical Necessity – No Issues with Clinical Documentation, Coding

Based on the documents available to me, the government has not examined or has not produced evidence that it has examined any patient's medical records which would include the progress notes of the patient's primary care physician, the primary care physician's order for a test such as an ECG, EKG or EEG, the diagnosis and diagnosis codes for the patient, or the final report

generated from the test by the software. In the Grand Jury Indictment dated January 2016, the Government states that those claims that were paid must be medically necessary:

> The Medical Claims Process
>
> 11. The HCBPs reimbursed providers only for services that were medically necessary to the treatment of a beneficiary's illness or injury, were prescribed by a beneficiary's physician, and were provided in accordance with each of the HCBP's regulations and guidelines that governed whether a particular service would be reimbursed by the HCBP.

Figure 11 - Grand Jury Indictment January 2016 page 4

Failure to Prove Lack of Medical Necessity - No Evidence of Insurance Audits

Based on the information available to me, there is no evidence that any payor routinely denied claims.

Failure to Prove That a Datrix DR512 Was Used – No Final Reports Indicating DR512

Generally, a Final Report would include the listing of which medical device was used in the procedure. Based on the information available to me, there were no final reports provided.

Failure to Prove That a Datrix DR512 Was Used – No Form 855B

Independent Diagnostic Testing Facilities (IDTFs) such as Mr. Mirando's business are required to submit a form 855B to Medicare indicating which devices will be used in testing, the serial numbers of those devices[50], and which CPT codes will be billed. Based on the information available to me, there is no form 855B documenting whether only a Datrix DF512 was used or if other devices were used. I have found mention of other devices in document production and correspondence.

Failure to Prove That a Datrix DR512 Was Used – No Audit Trail

For the government to prove without a reasonable doubt that DR512 units were used, they would have to match each patient with that patient's progress notes, attending physician, the organization the physician uses to bill a payor by national provider ID (NPI), the diagnosis of the patient, the physician's order, the final report clearly showing the device used, the claim, and (if the coding or billing were in any way inappropriate) a pended or denied claim, or an audit by a payor which concluded that these items are not present. Based on the documents available to me, the Government has not provided such information. Without such information, the government cannot say that a provider billed inappropriately.

Patient Interview with Belen Perazzo Barber

There are several patient interviews that I have reviewed. I used patient Barber as a test and conducted an audit trail of his statements back to anything that corroborates his statements about medical documentation and found none.

I searched Aetna records produced by the FBI and found a spreadsheet but nothing that states that Aetna produced it.

According to Barber she had one cardiac test but there is no documentation from a physician or provider of any kind corroborating this. Patients in my experience can forget their treatment regimen and appointments which is why providers do reminders. The Interview was conducted around the date of entry by the FBI of the report, April 9, 2014.

Cross Check with Aetna Records for Patient Belen Perazzo Barber

I checked the Aetna claims report and I do find claims for this patient but they are over four years prior (see below).

1/19/10
1/12/10
1/16/10
1/19/10

1/13/10
1/23/10
1/12/10
1/12/10
1/16/10
1/19/10
1/16/10
1/13/10

Medical Necessity of Treatment Frequency for Patient Belen Perazzo Barber

Based on nationally accepted standards such as the National Correct Coding Initiative (NCCI) I find no irregularities with respect to codes used, diagnosis used, or patterns that indicate problems with medical necessity. This could indicate coding errors or other errors but the source documentation would be important to view to make that determination.

It may be possible that a cardiologist would prescribe this regimen, though no physician's medical opinion has been secured to opine on whether more than one 24-hour monitoring within a few weeks of the initial date of service appears to be medically appropriate or not.

FBI Interview with Jon Barron, Founder of Datrix

Much of the case hinges on whether EEG and ECG may be performed with the same device and what determines whether that is possible to do with one device. Of the 60,126 pages in this case that I can review, one phrase here is all the FBI appears to have and it does not appear to be a certainty that the device cannot do both EEG (brain) and ECG (cardiac / heart) related monitoring. If this is the case (see next section regarding FDA 510K), then in my opinion the government would need to tie this device to claims where the device was used for non-permitted procedures. I propose we develop a time line to show if and when non-permitted procedures were performed. My review indicates that there are no non-permitted procedures during the second (Oregon based) phase of business.

Device Frequency and Bandwidth

This statement to me does not satisfy the 'reasonable degree of certainty test' and certainly not 'without a reasonable doubt':

> *"BARRON believes that the DR512 model's sampling frequency rate is not sufficiently high enough to be used for an EEG. An EEG generally requires a higher sampling frequency rate than the model is capable of performing. Datrix also did not put in its FDA filing that performing an EEG was an intended use of the device. BARRON noted that the software used on the data collected from the DR512 would make no difference in whether an EEG could be conducted,* ***since the device itself isn't able to sample data sufficiently for the test***[1]*."*

FDA 510(K) Pre-Market Notifications

Please see separate 510(k) forms indicating that Datrix 512 and other FDA approved devices for brain diagnostic EEGs have the same frequency range and bandwidth as ECG and EKG for cardiac diagnostics. In fact, the frequency rate of the DR512 is the same as these devices.

[1] In fact, FDA 510(K) forms indicate that there are devices with exactly the same bandwidth and frequency that do perform both brain (EEG) and cardiac (ECG) and are approved by FDA to do so. See PowerPoint.

JON BARRON INC. dba
datrix

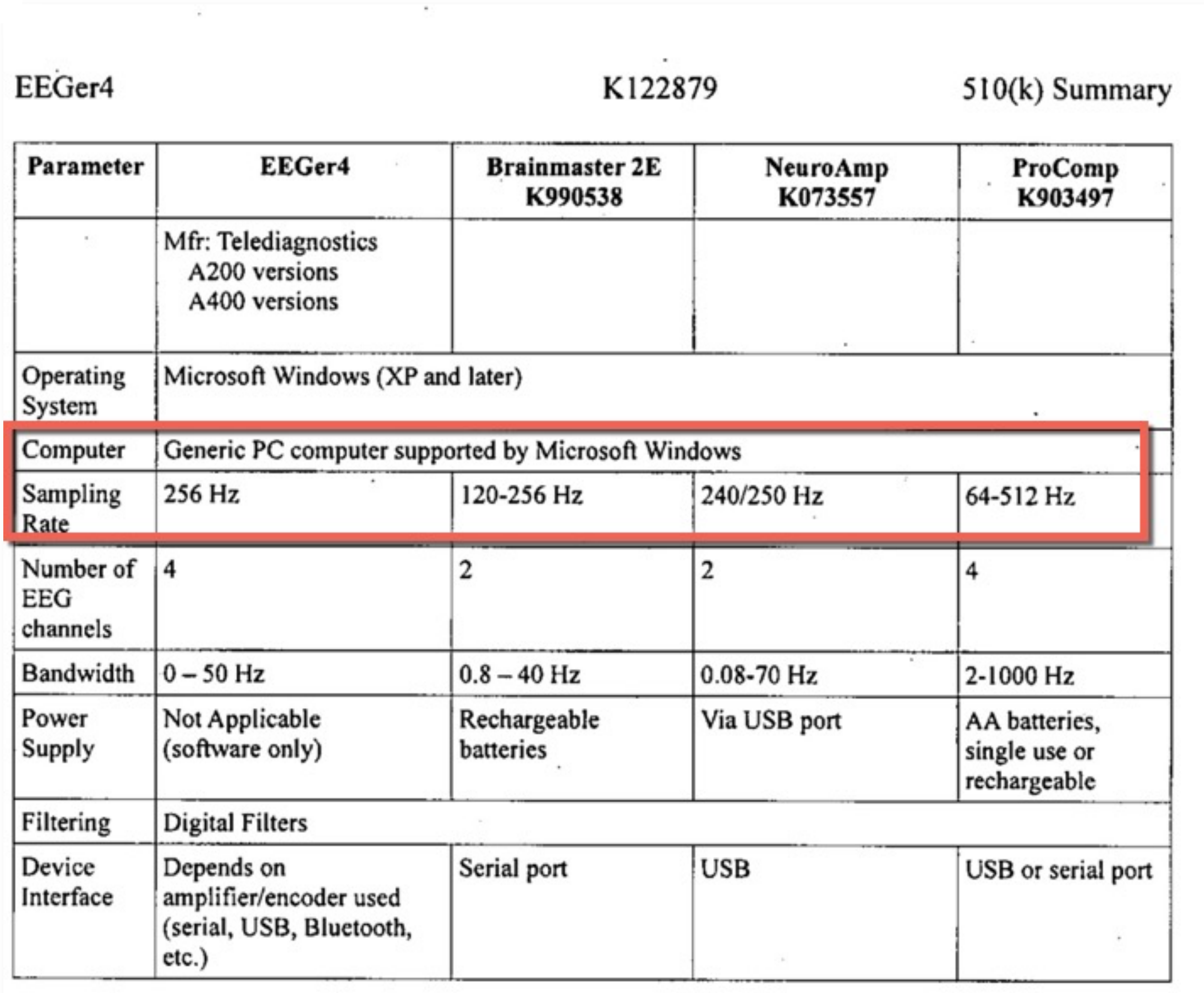
9 - 2

Predicate Device Comparison

The VX3 is substantially equivalent to other commercially distributed ECG Holter recorders. The following chart compares the VX3 with its predecessor device (Datrix DR512 digital Holter recorder (510(k): K982975), and another predicate device, (Braemar DXP1000 digital Holter recorder (510(k): K993618) with pacemaker pulse detection).

Specification	Datrix VX3	Datrix DR512	Braemar DXP1000*
Functional			
ECG Channels	2 or 3	2 or 3	2 or 3
Resolution	8 or 10 bit (programmable)	8 bit	12-bit sampling/ 10-bit recording
Sample Rate	128 to 512 per channel/sec, programmable	128 to 512 per channel/sec, programmable	256 samples per second
Recording Duration	24 or 48 hours, programmable	24 hours	24 or 48 hours
Memory Type	Non-volatile flash	Non-volatile flash	Non-volatile flash
Data Transfer	Removable flashcard	Removable flashcard	USB interface
Liquid Crystal Display	Yes	No	Yes
Keypad	Yes, optional	No	Yes
Pacemaker Pulse Detection	Yes, optional	No	Yes
Physical			

Figure 12 - Datrix Devices use sample rate of 128 to 512 per channel/sec



EEGer4 K122879 510(k) Summary

Parameter	EEGer4	Brainmaster 2E K990538	NeuroAmp K073557	ProComp K903497
	Mfr: Telediagnostics A200 versions A400 versions			
Operating System	Microsoft Windows (XP and later)			
Computer	Generic PC computer supported by Microsoft Windows			
Sampling Rate	256 Hz	120-256 Hz	240/250 Hz	64-512 Hz
Number of EEG channels	4	2	2	4
Bandwidth	0 – 50 Hz	0.8 – 40 Hz	0.08-70 Hz	2-1000 Hz
Power Supply	Not Applicable (software only)	Rechargeable batteries	Via USB port	AA batteries, single use or rechargeable
Filtering	Digital Filters			
Device Interface	Depends on amplifier/encoder used (serial, USB, Bluetooth, etc.)	Serial port	USB	USB or serial port

Figure 13 - EEG Software LLC FDA 510K with same sampling rate ranges from 64 to 512 Hz as Datrix Devices

V. Conclusions

Based on the information available to me with a reasonable degree of certainty:

1. The PSR / PIR has mathematical errors of 6% to 12% in the summation of Counts 1-15 of fraud.

2. There are only seven (7) patients analyzed in the indictment and four (4) in the PIR / PSR which represent 137 claims out of over 31,000 claims in the data produced by the Government.

3. The Government's methodologies do not form the basis for a statistically valid method to extrapolate to over $7 million in fraudulent bills and $2 million in fraudulent receipts and results in a 19% certainty level regarding total fraud rather than the industry standard of 51% reasonable degree of certainty.

4. Duplicate charges are overstated. There are 90 actual duplicates which could be fraud or could be simply duplicate requests for payment. There are over 31,000 claims and a small percentage of these claims are 'adjacent' to each other by date of service.

5. There were no audits conducted by any insurance company that confirmed the existence of fraud, and I have no data to conduct a statistically valid sample and project fraudulent claims in a damages analysis, beyond $10,695.06.

6. It appears inconclusive which device was used to perform alleged fraudulent 'unable to perform' procedures.

7. Without a complete analysis of physician interviews, patient documentation and diagnosis, claims data and reimbursement tied by individual medical service, it is impossible to determine how much if any fraud was committed beyond seven patients analyzed.

8. Based on the information available to me, I do not know if Mr. Mirando or others submitted the insurance claims produced by the Government, but in total Holter Lab's cannot in my opinion be held to damages or loss calculations beyond the amount of $10,695.06.

9. Since the suspect and duplicate claims are unproven in my opinion to be fraud, $2,587,360.23 for these amounts, minus $1,339.180.04 in unpaid claims as an offset, minus $538,515.73 in unproven duplicates, minus $2,574,940 for unable to perform procedures, plus the accurate fraud counts mathematical total of $10,695.06 equals a negative number of ($1,854,580.95) which means that subject to further audits, the payors (health insurance firms) in this case may owe Holter Labs for unpaid claims.

		Billed	**Intended Loss**	**Paid (Actual Loss)**	**Total**
Suspect + Dup		$8,008,875.45	$2,482,751.39	$ 2,587,360.23	$ 2,587,360.23
Less : Unpaid				$ 1,339,180.04	$ 1,339,180.04
		Subtotal - Suspect + Duplicates Less Offset			**$ 1,248,180.19**
Less: unproven duplicates					$ 538,515.73
		Subtotal - Above Less Unproven Duplicates			**$ 709,664.46**
Less: unproven unable to perform					$ 2,574,940.47
		Subtotal - Above Less Unproven Unable to Perform			**$ (1,865,276.01)**
Add: accurate mathematical total for Counts 1-15					$ 10,695.06
		Negative number means payors owe Holter Labs			**$ (1,854,580.95)**

Figure 14 - Summary of Calculations, with Mathematical Corrections by Arrigo

In my opinion net damages are zero (mathematically a negative number which may indicate payors owe money for unpaid claims). Though in my opinion the Government methodology could have been stronger, I have left the amounts of $10,695.06 (the correct mathematical total) my calculations.

10. I am also aware from other loss and damages calculations where I was retained by counsel for the Relator in San Francisco that the 'foreseeable' loss in health care fraud cases, is the amount billed to an insurer, if not rebutted, <u>however</u>, the parties may introduce additional

evidence to support arguments that the amount billed overestimates or understates the defendant's intent (*See* U.S. v Popov and U.S. v. Prakash).[51]

11. Therefore, in my opinion the actual, foreseeable amount of fraud is at most 31% of the billed amounts based on widely known industry practices and even data published by the Government itself.

12. Intended fraud in this case is, at most 31% of the billed amount, and it is not reasonable to add 18 points to the sentencing guideline formulas, and, based on the statistically invalid and unreliable methodology employed by the Government the payors in this case may owe Holter Labs money.

13. The PIR / PSR states in paragraph 37 that the unable to perform payments are $3,025,329.47 and that this is due as restitution. This is **not** correct.

    ix. First as noted elsewhere in this report the sample size used by the Government produces an unreliable 19% confidence level vs. the standard of 51%

    x. Second, even if it were accepted using appropriate sampling methods that all paid claims for 'unable to perform' procedures were fraudulent the correct total is $2,930,852.64 which is an error of 3.22% in the Government's calculations.

    xi. Third, as noted elsewhere the Government fails to link all of the claims associated with the procedures and CPT codes in question to the exact device that was used to perform the procedure. I have not data to conclude any amount for 'unable to perform' codes and presume that in the absence of provable data and statistically valid methods that this is zero.

I specifically reserve the right to add to, amend or subtract from the report as new evidence becomes available or the opinions of other experts are reviewed and considered.

Signed,

Michael F. Arrigo

Exhibit A – Curriculum Vitae

See separate document with CV.

Exhibit B – Principles and Methods

Data and Methods for Calculating Charges v. Payments

Data from the Health Affairs analysis, CMS, and American Hospital Association was used to collect health care provider characteristics. Data was obtained from the 2011 American Hospital Association annual survey, which provides demographic and structural information about American providers, and matched to CMS data using the Medicare Provider number or the name of the provider. Health care provider financial information was obtained from 2011 Medicare Cost Reports.[52] Information on whether the provider is currently participating in an accountable care organization (ACO) was obtained from Leavitt Partners' database of ACOs. Location information is based on the United States Office of Management and Budget-designated statistical areas using a zip code to statistical area crosswalk. Full data for all specifications of the analysis were available for 2,925 (87.7 percent) of the CMS providers which includes inpatient and outpatient data.

Provider characteristics that were evaluated include those associated with provider size (determined by bed size); affiliation with a system; ownership (not-for-profit, government owned or investor owned); academic status (determined by whether the provider is accredited to offer a residency program); whether the provider offered an insurance product (health maintenance organization, preferred provider organization or indemnity insurance plan); whether the provider participated in a joint venture with physicians; location (metropolitan, micropolitan or rural area); the percent of total payments the provider received through capitated payments; the percent of provider discharges that are covered by Medicare and Medicaid; the provider operating margin (calculated by dividing net operating income by net operating revenue which is total patient revenue less contractual allowances and patient discounts); and whether the provider participated in an ACO.

The unit of analysis is the ratio of charges billed to Medicare to the amount reimbursed by Medicare. Providers that receive Medicare payments are required to accept them for the full value of the care and cannot bill the patients for the difference between Medicare's reimbursement and the billed charges, meaning that the providers are implicitly willing to accept the amount paid by Medicare for the services rendered. Higher ratio values indicate higher charges compared to the reimbursement level they are willing to accept for the services rendered. The provider characteristics' association with the charge-to-reimbursement ratio was

calculated with ordinary least squares linear regression using discharge-adjusted average provider ratios across all DRGs.

Results

There is significant variation of charge-to-reimbursement ratios. Across all providers and all DRGs, charges were 3.77 (standard deviation=1.83) times as high as Medicare reimbursements (range .19 to 23.6, median=3.337). Provider ratios (combining all DRGs at the provider level) ranged from 0.42 to 16.23.

Exhibit 1 below contains the coefficients of the regression analysis of the association of provider characteristics and the charge-to-reimbursement ratio. Of the evaluated characteristics, 12 of 14 were significantly associated with either an increase or decrease in the charge-to-reimbursement ratio ($p<.05$). The factors associated with a substantial increase in the charge-to-reimbursement ratio include being an investor-owned provider (compared to being a not-for-profit provider), being part of a provider system, participating in a joint venture with physicians and being larger in terms of bed size. Accepting a higher percentage of care through capitated payments and having a higher operating margin were significantly associated with higher charge-to-reimbursement ratios, but the magnitudes of both associations were trivial. Large, investor owned providers that are part of provider systems and located in metropolitan areas thus tend to have the largest charge-to-reimbursement ratio.

The factors associated with substantial decreases in the charge-to-reimbursement ratio include the location (either being in a rural or micropolitan area as opposed to a metropolitan area), being an academic medical center, offering an insurance product, and being government owned (as opposed to not-for-profit). A higher percent of Medicaid patients is associated with a significant, but minor, decrease in the ratio. Small, unaffiliated, government-owned providers located in rural areas tend to have the lowest ratio.

Several factors were not significantly associated with the charge-to-reimbursement ratio. These include the percentage of provider discharges that are reimbursed by Medicare and whether the provider participates in an ACO.

Conclusion

It is not surprising that there is variability in charge-to-reimbursement ratios among providers, but the degree of that variability is substantial. Some providers' (35 out of 3337) average

Medicare charge was for less than they were actually reimbursed, while others billed, on average, as much as 16 times what they were paid by Medicare. The average degree of the charge-to-reimbursement ratio is also surprising, with providers charging nearly four times, on average, what they accept as reimbursement.

From a consumer's perspective, the disadvantages of higher charges that are not strongly correlated with actual reimbursement rates are real. Specifically, charges uncorrelated with actual reimbursements make it difficult, if not impossible, for patients to compare providers, eliminating any potential financial benefit of consumer-directed choice of providers. A movement toward more transparent pricing may enable patients to become more involved in the cost of their care.

Exhibit 1: Hospital Characteristics and Association with Ratio of Hospital Charges to Reimbursement

Factor	Change in Ratio	p-value
Bed Size (100 bed increase)	0.14	<.001
Member of Hospital System	0.592	<.001
Investor Owned Hospital (compared to Not-For-Profit)	1.064	<.001
Government Owned Hospital (compared to Not-For-Profit)	-0.21	0.012
Academic Medical Center	-0.545	<.001
Offers Insurance Product	-0.269	<.001
Participates in Joint Venture with Physicians	0.168	0.007
Located in Micropolitan Area (compared to Metropolitan Area)	-0.776	<.001
Located in Rural Area (compared to Metropolitan Area)	-1.125	<.001
Percent of Patient Revenue Paid by Capitation (1% Increase)	0.027	0.002
Percent of Discharges paid by Medicare (1% increase)	0.002	0.431
Percent of Discharges paid by Medicaid (1% Increase)	-0.007	0.037
Operating Margin (1% Increase)	0.003	0.049
Hospital participates in an Accountable Care Organization	-0.067	0.325
Baseline	3.002	<.001

Data from CMS, AHA, and author's analysis.

Clinician's Medical Documentation and Medical Coding Review, Where Applicable

Medical Coding

Medical coding and billing is a complex and regulated function that is part of the process of transforming a patient's medical record into financial reimbursement for services provided by health care providers. Medical coding does not stand alone however in securing reimbursement for billable health care procedures, services or equipment provided. Clinical documentation provided by licensed professionals supports the use of medical codes (*see* next section).

Fundamental Purpose of Clinical Documentation

The American Health Lawyers explained the importance the linkage between Medical Coding, Medical Necessity and Clinical Documentation. *(See* AHLA - Timothy P. Blanchard and Joan Ragsdale – Clinical Documentation) stating,

> "Clinical documentation serves several important purposes in healthcare, including:
>
> 1. Facilitating efficient and effective delivery of high quality health care services.
> 2. Satisfying Conditions of Participation (COP) in Medicare (and other payers) [53]
> 3. Satisfying Conditions of Payment, [54] including, but not limited to the reasonableness and medical necessity of items and services (or that this standard is not applicable to the particular services in question).
> 4. Complying with state licensing and professional practice laws and regulations.
> 5. Demonstrating satisfaction of performance metrics and targets.
> 6. Defending allegations of failure to comply with or satisfy any of the above and/or false claims and health care fraud."

Most importantly, clinical documentation in the medical record for each individual patient is required by applicable state and federal statutes and regulations, including facility-licensing rules and medical/professional practice acts. While the language and details of state statutes and regulations vary somewhat, all states essentially require providers to "maintain adequate and accurate records relating to the provision of services to their patients." The adequacy of clinical documentation may depend on the intended use of the information by the reader (the physician, a

covering or co-treating physician, consulting specialists, hospitalists, nurses, therapists, and other provider or nursing facility personnel, medical reviewers, medical staff peer review, payer reviewers, program integrity and law enforcement personnel, administrative law judges and courts, and increasingly patients and family members). Providers must recognize that any or all of these persons may have occasion to review and evaluate (or seek to understand) the medical record entries made by the provider."

Documentation of Medical Necessity Required for Medical Coding and Payment

Under the Medicare statute[55], no Medicare payment shall be made for items or services that are not reasonable and necessary for the diagnosis or treatment of illness or injury. [56] Although these statutes were originally established for Medicare they have been adopted nationwide as the standard payors use to determine if a medical procedure is medically necessary. Clinical documentation is necessary to establish that services provided were reasonable and necessary. It is important to recognize, moreover, that adequate clinical documentation is a condition of payment distinct from the requirement of medical necessity itself. [57] It has been held that Medicare claim form certifications (whether submitted on paper or electronically) are representations "that the person signing the claim has acquired sufficient information **and made the requisite documentation** to prove that the services were provided as claimed." [58]

Failure to provide required documentation to support Medicare and Medicaid claims is a basis for exclusion from the programs, [59] and clinical documentation is required to satisfy requirements for QIO reviews. [60]

In a well-documented medical record, there will frequently be several types and sources of documentation supporting the necessity of the services provided, but the primary objective in preparing clinical documentation should be to assure that a qualified reviewer can easily determine what was done for the patient and the clinical rationale for the services provided.

The Medical Necessity Documentation Requirements vary with type of items and services involved. In some cases, specific forms of orders are required. In others, additional specific types of documentation must be prepared (*e.g.,* certifications of medical necessity). In general, however, **orders and other specific documentation must be backed up by entries in the medical record**

demonstrating the ordering physician's involvement in the case and medical decision making or rationale for the services ordered.

One component in determining medical costs is accomplished by reviewing medical codes provided in patient documentation. Medical diagnosis codes (usually ICD-9 or ICD-10) are entered by coders at health care providers as a result of a licensed physician's diagnosis at a health care provider. Procedure codes (usually CPT or HCPCS) are used to describe billable medical procedures that are translated into economic value for health care claims. I am relying on the diagnosis and the codes that exist in the documentation and I review the documentation and coding for the way they are used to derive medical costs.

Patient Condition and Diagnosis

Since a licensed clinician must determine when a medical procedure is appropriate (*See* Code of Federal Regulations 42 CFR §410.32 [61]*)*, the patient's medical records must clearly document the medical necessity for the test (*See* Title XVIII of the Social Security Act, §1833(e), which prohibits Medicare or other payor's payment for any claim lacking the necessary documentation to process the claim.)

If the physician does not indicate a diagnosis, then a medical procedure may be determined by an insurance company (whether private payor or Medicare and Medicaid) to be non-medically necessary and therefore a claim for reimbursement of this procedure may be denied.

Billing, Claims Denials and Medical Review

If a claim for reimbursement of any medical procedures submitted to a payor results in denial, it is appropriate to ask for a review. During a review, BOTH the patient's condition and diagnosis codes as well as the data collected during the medical assessment, medical procedure or diagnostic test may be required. The responsibility to provide this information falls to the medical professional (health care provider) not to the billing and coding function.

Payors must decide whether to take one of three actions when presented with a claim for payment for services:

- **Pay** - When the claim is received the service is paid at some defined level assuming appropriate conditions are met.
- **Pend** – Hold payment of the claim for some level of review or request for additional information
- **Deny** – Disallow payment of the claim for any number of reasons that may be related to benefits, coverage limits, medical necessity, evidence of medical effectiveness, medical appropriateness or any number of other reasons that may or may not have to do with medical reasons. [62]

Medical Policy and Coverage Determinations from the Payor

If maximum out of pocket exceeds the cost of a treatment plan under the ACA, then the value of the cost of the treatment is used. If the maximum out of pocket is less than the treatment cost, then maximum lifetime out of pocket value is used for those procedures deemed medically necessary in the opinion of insurance companies based on my knowledge of industry best practices and guidelines and applicable statutes.

I may consider Medical Policies and guidelines of payors applicable in the geography where medical procedures are rendered may provide claims payment determination for procedures identified by CPT, HCPCS and ICD-9[2], ICD-10 CM or ICD-10 PCS coding. Reimbursement guidelines are developed by clinical staff that work with payors and include yearly coding updates, periodic reviews of specialty areas based on input from specialty societies and physician committees and updated logic based on current coding conventions.

Out of network "non-par" payments are made by payors to providers who are not in the payor's contracted provider network. These providers' payments may be subject to delays. Furthermore, out of network payments may be subject to higher special investigation unit (SIU) examinations.

Therefore, as a solution to delayed payments, some Providers are willing to accept reimbursement via a discount settlement network by signing an agreement in perpetuity that they will accept a lower reimbursement for all future procedures of the same type (usually

[2] ICD-9 coding standard in effect until October 1, 2015 and replaced by ICD-10

described by CPT code or ICD-9 or ICD-10 code) when the claim is submitted for a specific payor in lieu of delays for pended claims. Only claims that are adjudicated by the payor and meet the initial policy plan design are forwarded for discount settlement so the payor is ensured that the procedure meets initial UM, COB, Case Management and medical necessity review.

So called "out of network" discount settlement payments provide data points to help determine what the free market value of a procedure are because the provider has a choice to wait or accept reimbursement quickly at a discount.

ICD-9 or ICD-10 Diagnosis and Procedure Codes - Medical patient records in this case may contain ICD-9 diagnosis codes which are used for both inpatient and outpatient diagnosis, and ICD-9 procedure codes which are used exclusively for inpatient procedures. (ICD-9 stands for the International Classification of Diseases, 9th edition from the World Health Organization[3], localized for the U.S. market). The U.S. developed its own procedure coding system (ICD-9-CM, Volume 3) for inpatient hospital services in the late 1970's to use with ICD-9-CM, Volumes 1 and 2 for diagnoses. Since 1979, procedures performed in hospitals have been coded for hospital statistics and on hospital claims, using ICD-9-CM, Vol. 3 and the ICD-9 standard is managed under the authority of the NCVHS. NCVHS is authorized under Section 306(k) of the Public Health Service Act, as amended, and codified at Title 42, Chapter 6A, Subchapter II, Part A, § 242k. The Committee is governed by provisions of Public Law 92-463, as amended, (5 U.S.C. App. 2), which sets forth standards for the formation and use of advisory committees. I cross-referenced the numeric references to codes found in documents provided by counsel and compared them with corresponding descriptive references to confirm descriptions of a medical procedure performed in the inpatient setting and the cost of those procedures locally and nationally, the coverage determinations and reimbursement rates under the patient's health plan, and Medicare reimbursement rates. The ICD-9 diagnosis code(s) and correlated ICD-9 procedure codes are

[3] The World Health Organization (WHO) is the authoritative body that directs and coordinates international health within the United Nations' system. The World Health Assembly is the supreme decision-making body for WHO. WHO generally meets in Geneva in May each year, and is attended by delegations from all 194 Member States including the United States. Source: http://www.who.int/governance/en/

examined for reasonableness and peer-reviewed by an AHIMA[4] certified coder under my direction and control. Any procedures rendered after October 1, 2015 may contain ICD-10 diagnosis codes and ICD-10 PCS procedure codes for inpatient procedures only.

Current Procedural Terminology ("CPT") codes for outpatient procedures and professional fees charged by physicians - Some outpatient medical patient records if applicable, contain CPT procedure codes, (Current Procedural Terminology or CPT®[5] codes and descriptions). The ICD-9 (see below) diagnosis code(s) correlated with the CPT-4 procedure codes are examined for reasonableness and peer-reviewed by an AAPC[63] certified coder under my direction and control.

Outpatient Prospective Payment System (OPPS), Medicare GAF

Some types of procedures are adjusted geographically for local markets using U.S. Office of Management and Budget (OMB) statistical data adjusted annually for wage indices using Medicare Geographic Adjustment Factors (MGAF). In 2007, payment for the technical component (TC) portion of a radiology service was limited to the lesser of the Medicare Physician Fee Schedule (MPFS) amount or the Outpatient Prospective Payment System (OPPS) amount. Effective January 1, 2012, CMS applied a 25 percent payment reduction for the professional component (PC) of second and subsequent imaging services furnished by the same provider including physicians in a group practice to the same patient in the same session on the same day. The basis for MPFS in determining the value of work is 42 CFR Parts 405, 410, 411, 414, 423, and 425.

National Percentile Levels to Establish Customary Medical Charges

In order to adjust the national average to specific geographic areas, geographic adjustment factors have been calculated by taking the difference from the national average for each service area across

[4] AHIMA – The American Health Information Management Association is an accepted standards education and certification organization for medical coder certification, especially for inpatient coding.

[5] CPT is a registered trademark of the American Medical Association (AMA)

all service areas for each geographic area. Averages of charges were then taken across the service areas and percentiles (50th, 75th and 90th) to create one overall difference from the national average. This amount is an aggregated estimate and individual procedure codes may not reflect this difference from the national average. These GAFs were developed by Optum using FAIR Health, Inc. data.

I used charges at the 50th percentile, (50% of charges are below this rate; 50% of charges are at or above this rate) and 75th percentile (75% of charges are below this rate; 25% of charges are at or above this rate). The reason for the 50th percentile level is that it is a relatively low amount matching Medicaid pricing for contracted providers. In my opinion this Plaintiff, if a U.S. citizen current house hold income would potentially be a Medicaid insured. If the Plaintiff was insured by other sources, then the percentile charges would be higher at a maximum amount in my opinion of 75th percentile. Texas Medicaid rates include a broad spectrum of the population with household incomes from zero to 133% of the Federal Poverty Level (FPL) calculated as Modified Adjusted Gross income (MAGI). [64]

Medi-Cal rates at the 50th percentile lag substantially behind commercial payor rates. [65]

Ambulatory Patient Classification (APC)

APCs are an outpatient prospective payment system applicable only to ambulatory surgery centers (ASCs). To be deemed an ASC the center must operate,

> "...independently or as hospitals, and have no impact on physician payments under the Medicare Physician **Fee Schedule**." Additionally, according to the U.S. HHS Centers for Medicare and Medicaid, "… an ASC is a distinct entity that operates exclusively for the purpose of furnishing surgical services to patients who do not require hospitalization and in which the expected duration of services does not exceed 24 hours following admission. This definition applies to the ASC no matter who the payor is for the ASC's services. Additionally, services to Medicare patients are not expected to require active medical monitoring at midnight when furnished in an ASC (see discussion in the ASC Payment section on pages 2 through 4). You must be certified as meeting the requirements for an ASC and enter into an agreement with the Centers for Medicare & Medicaid Services (CMS) to be eligible for Medicare payment. An ASC can be either:

- Independent (not part of a provider of services or any other facility); or
- Operated by a hospital (under the common ownership, licensure, or control of a hospital). An ASC operated by a hospital must meet additional criteria (*See* ICN 006819 December 2015 on the CMS website) [66] including Ambulatory Surgical Center Conditions for Coverage and Associated Interpretive Guidelines for Medicare Certification**.**

... If the patient is admitted from a hospital clinic or ED, then there is no **APC** payment, and Medicare will pay the hospital under inpatient DRG methodology.
In most cases, the unit of payment under the OPPS is the APC. CMS assigns individual services (Healthcare Common Procedure Coding System [HCPCS] codes) to APCs based on similar clinical characteristics and similar costs. The payment rate and copayment calculated for an APC apply to each service within the APC. Sometimes new services are assigned to New Technology APCs, which are based on similarity of resource use only, until cost data are available to permit assignment to a clinical APC. The payment rate for a New Technology APC is set at the midpoint of the applicable New Technology APC's cost range. Some services are paid separately, including but not limited to:

- Many surgical, diagnostic, and nonsurgical therapeutic procedures;
- Blood and blood products;
- Most clinic and emergency department visits;
- Some drugs, biologicals, and radiopharmaceuticals;
- Brachytherapy sources;
- Corneal tissue acquisition costs; and
- Certain preventive services.

Partial hospitalization is paid on a per diem basis, with payment rates dependent on the number of individual services provided to the patient in one day[67].

Professional Components, Technical Components, Relative Value Units

Where applicable for imaging services, charges are split into technical and professional components (the TC and PC), each separately billable[68].

A relative value is a numeric ranking assigned to a procedure relating it to other procedures in terms of the time, work and costs associated with the procedure. The Medicare relative value units are based on the Resource Based Relative Value Scale (RBRVS) update and published

yearly by CMS. The total value is the sum of three components: a work value, a practice expense (PE) value, and a malpractice (MP) expense value. The PE value has been further subdivided into a facility value and a non-facility value. The basis for RVUs in determining the value of work is 42 CFR Parts 405, 410, 411, 414, 423, and 425.

The RVU ratio between TC and PC can vary by type of diagnostic image, and the ratios are published by the Centers for Medicare and Medicaid.

The PC is indicated in claims using a "Modifier 26." Certain procedures are a combination of a physician or other qualified health care professional component and a technical component. When the physician or other qualified health care professional component is reported separately, the service may be identified by adding modifier 26 to the usual procedure number or CPT code[69].

Authoritative Economic, Scientific and Standards Organizations for CPT, ICD

Current Procedural Terminology or CPT Codes for Outpatient Procedures

Current Procedural Terminology or CPT® codes and descriptions, are copyrights of the American Medical Association Current Procedural Terminology (CPT®), Fourth Edition, is a standardized listing of descriptive terms and identifying codes for reporting medical services and procedures. The purpose of CPT is to provide a uniform language that accurately describes medical, surgical, and diagnostic services, and thereby serves as an effective means for reliable nationwide communication among physicians and other healthcare providers, patients, and third parties[70].

CPT was first developed by the AMA in 1966 and is used for the billing of physician services and non-inpatient medical procedures in the U.S. The current version, CPT-4 is maintained by the AMA and is an accepted standard by the National Committee on Vital Statistics or NCVHS[71]. NCVHS is authorized under Section 306(k) of the Public Health Service Act, as amended, and codified at Title 42, Chapter 6A, Subchapter II, Part A, § 242k. The Committee is governed by provisions of Public Law 92-463, as amended, (5 U.S.C. App. 2), which sets forth standards for the formation and use of advisory committees. I cross-referenced the numeric references to codes found in documents provided by counsel and compared them with corresponding AMA references to confirm descriptions of a medical procedure performed in the outpatient setting and the cost of

those procedures locally and nationally, the coverage determinations and reimbursement rates under the patient's health plan, and Medicare reimbursement rates.

The CPT Editorial Panel is tasked with ensuring that CPT codes remain up to date and reflect the latest medical care provided to patients. In order to do this, the Panel maintains an open process and convenes meetings three times per year to solicit the direct input of practicing physicians, medical device manufacturers, developers of the latest diagnostic tests, and advisors from over 100 societies representing physicians and other qualified healthcare professionals.

International Classification of Diseases (ICD) for all diagnoses and inpatient procedures

Methodology for Analysis of Duplicate Claims

The Claim files were first analyzed for what the Government alleges are "suspect" procedures designated by CPT codes as delineated in the Government's indictment.

Although in my opinion there are mitigating circumstances as to whether these are all suspect procedures, I checked the Government's methodology and calculations first.

Therefore, any claim that contained CPT codes below were flagged as "Suspect" CPT codes:

1. **93025** - Microvolt T-wave alternans for assessment of ventricular arrhythmias

2. **93229** - External mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis and greater than 24 hours of accessible ECG data storage (retrievable with query) with ECG triggered and patient selected events transmitted to a remote attended surveillance center for up to 30 days; technical support for connection and patient instructions for use, attended surveillance, analysis and transmission of daily and emergent data reports as prescribed by a physician or other qualified health care professional [72]

3. **93271** - External patient and, when performed, auto activated electrocardiographic rhythm derived event recording with symptom-related memory loop with remote download capability up to 30 days, 24-hour attended monitoring; transmission and analysis

4. **95806 -** Sleep study, unattended, simultaneous recording of, heart rate, oxygen saturation, respiratory airflow, and respiratory effort (e.g., thoracoabdominal movement

5. **95827 -** Electroencephalogram (EEG); all night recording

The totals were obtained for the amount billed and paid for these Claims flagged as "suspect".

The Claims were then analyzed for Duplicate Claims. All "Suspect" Claims were excluded to avoid counting these claims twice. Any claim that had the same Patient ID, date of service and CPT codes were identified as a duplicate Claim. The totals were obtained for the Amount Billed and Amount Paid for the Duplicates.

The Unpaid Claims were identified by first excluding all "Suspect" Claims and Duplicate Claims. The remaining claims were investigated for claims that were submitted but not paid (the paid amount = 0). These claims were summed to find the total of Unpaid Claims.

Methodology for Unpaid Claims Analysis

1. Overview of Claims date reviewed

   Claims data was provided by the Government to counsel for Mirando who provided them for the analysis.

   Claims data was received for the following payors:

   - Aetna,
   - Anthem,
   - BCBS,
   - Blue Choice,
   - Cigna,
   - Coventry,
   - Emblem,
   - GEHA,
   - HealthFirst,
   - Highmark,
   - Humana,
   - IHC Health Solutions,
   - Independent Blue Cross,
   - Independent Health,
   - Kaiser,
   - Medicare,
   - Premera Blue Cross,
   - TriCare,
   - United Health Care,
   - Wellcare Health
   - XL Health
   - Medicare.

2. The following table lists the total amount billed and total amount paid for each health insurer, including valid claims.

Insurance Company	Total Claims Billed	Paid
Aetna Life Insurance Company	$1,792,645.32	$462,666.82
Anthem Inc/ Anthem Blue Cross/WellPoint	$1,725,696.00	$403,490.05
BCBS 2005 -2008	$9,253.00	$4,222.84
Blue Choice	$26,778.00	$12,195.85
Blue Cross Blue Shield of Alabama	$227,549.00	$125,054.87
BCBS of Arkansas (Claim file Password Protected)		
Blue Cross Blue Shield of Florida	$39,862.85	$8,908.92
Blue Cross Blue Shield of Hawaii	$3,642.00	$1,723.00
Blue Cross Blue Shield of Minnesota	$30,162.00	$14,825.49
Blue Cross Blue Shield of New Jersey	$33,162.00	$10,847.90
Blue Cross & Blue Shield of Rhode Island	$24,909.00	$11,989.48
Blue Cross Blue Shield of South Carolina	$98,818.00	$38,667.13
Cigna	$872,327.36	$285,388.72
Coventry Health Care	$74,263.00	$26,692.50
Emblem Health	$52,730.84	$9,235.84
GEHA	$37,682.00	$15,138.21
Healthfirst	$18,695.00	$83.84
Highmark Blue Cross	$391,777.00	$185,592.49
Humana	$1,598,745.03	$389,215.50
IHC Health Solutions	$2,710.00	$427.00
Independence Blue Cross	$193,696.00	$82,103.25
Independent Health	$175,400.00	$123,659.32
Kaiser Permanente	$7,792.00	$5,432.59
Medicare thru 4/17/2016)	$983,390.00	$352,300.34
Premera Blue Cross	$28,030.00	$8,343.73
Tricare (Claim file Password Protected)		
United Health Group (Optum)	$4,039,106.06	$1,322,595.28
WellCare Health Plans, Inc.	$14,285.00	$6,231.34
XL Health	$15,953.50	$8,191.94
Total	**$12,519,059.96**	**$3,915,224.24**

Findings:

a. The Government data that was produced does not represent all claims submitted by Holter Labs, only those claims for that period that the Government determined relevant for its investigation and Indictment.

b. The Government's determination of total claims by payor from January 4, 2005 through March 2016 are:[73]

Insurance Company	Sum of Billed Amount	Sum of Paid Amount
AETNA	$1,681,855.44	$437,492.41
Anthem Blue Cross/WellPoint	$1,260,463.00	$326,071.53
BCBS of Alabama	$227,504.00	$124,913.29
BCBS of Arkansas	$7,090.00	$3,034.60
BCBS of Florida	$34,155.90	$8,822.97
BCBS of Hawaii	$3,926.00	$2,021.07
BCBS of Minnesota	$24,347.00	$12,984.33
BCBS of New Jersey	$33,162.00	$10,847.90
BCBS of Rhode Island	$22,644.00	$11,989.48
BCBS of South Carolina	$98,818.00	$38,667.13
Cigna	$920,076.62	$300,576.52
Coventry Health	$46,906.00	$19,876.51
Emblem Health	$44,710.84	$9,113.12
GEHA	$37,682.00	$15,138.21
Healthfirst	$18,075.00	$6,322.26
Highmark Blue Cross	$391,777.00	$185,267.49
Humana	$1,031,990.95	$284,422.29
IHC Health Solutions	$8,980.00	$1,666.11
Independence Blue Cross	$186,588.00	$83,388.42
Independent Health	$237,068.00	$161,428.50
Kaiser Permanente	$19,501.00	$11,302.93
Premera Blue Cross	$28,030.00	$8,343.73
Tricare	$289,901.00	$112,230.68
United Health Group	$3,631,111.68	$1,314,383.06
Wellcare	$14,285.00	$6,231.34
XL Health	$15,858.50	$8,139.29
(blank)		
Grand Total	**$10,316,506.93**	**$3,504,675.17**

3. The five CPT codes considered to be potential fraud by the US will be referred to as "suspect" CPT codes:

93025 Microvolt T-wave alternans for assessment of ventricular arrhythmias

93229 External mobile cardiovascular telemetry with ECG recording, technical support for connection and patient instruction for use, attended surveillance, analysis and physician prescribed transmission of daily and emergent data reports.

93271 External patient and, when performed, auto activation ECG rhythm derived event recording with symptom related memory loop with remote download capability up to 30 da. 24-hour attended monitoring, includes transmission and analysis

95806 Sleep study, unattended, simultaneous recording of heart rate, oxygen saturation, respiratory airflow, and respiratory effort

95827 Electoencephalogram, all night recording

4. Summary of Claims by CPT Code

For each health insurer, the claims data was further analyzed by looking at the CPT codes for the claims listed.

For example, the Anthem the total claims for each CPT are listed below:

	CPT	Amount Billed	Amount Paid
Anthem	93025	$5,774.00	$685.07
	93271	$206,715.00	$58,417.86
	95806	$5,675.00	$2,043.03
	95827	$94,375.00	$28,806.72
Total		$312,539.00	$89,952.68

Some Claim Files obtained contained only the CPT codes considered suspect and exclude appropriately billed claims.

5. The Claims files were analyzed for total of "suspect" CPT codes. For each claim file the total amount billed and paid from the "suspect" CPT codes was calculated. The totals for all claims data of "suspect" CPT codes:

Total Amount Billed "suspect' CPT Codes **$8,254,859.72**
Total Amount Paid "suspect' CPT Codes **$2,930,852.64**

6. Claims were analyzed for Duplicate Claims. A claim is considered a duplicate claim if the date of service and CPT code for the patient are the same. **<u>This excludes the "suspect" CPT Codes</u>**. The total duplicate claims for all files:

Total Amount Duplicates Billed	**$835,865.73**
Total Amount Duplicates Paid	**$12,419.76**

Unpaid Claims Excluding "Suspect" CPT codes and Duplicates

Insurance Company		
Aetna Life Insurance Company	$	275,199.63
Anthem Inc/ Anthem Blue Cross/Wellpoint	$	203,348.00
BCBS 2005 -2008	$	-
Blue Choice	$	1,106.00
Blue Cross Blue Shield of Alabama	$	6,091.00
BCBS of Arkansas (Claim file Password Protected)		
Blue Cross Blue Shield of Florida	$	8,158.00
Blue Cross Blue Shield of Hawaii	$	481.00
Blue Cross Blue Shield of Minnesota	$	4,419.00
Blue Cross Blue Shield of New Jersey	$	11,747.00
Blue Cross & Blue Shiled of Rhode Island	$	790.00
Blue Cross Blue Shield of South Carolina	$	5,118.00
Cigna	$	107,005.00
Coventry Health Care	$	16,660.00
Emblem Health	$	9,530.00
GEHA	$	2,460.00
Healthfirst	$	4,020.00
Highmark Blue Cross	$	-
Humana	$	128,329.50
IHC Health Solutions	$	1,380.00
Independence Blue Cross	$	15,628.00
Independent Health	$	300.00
Kaiser Permanente	$	2,147.00
Medicare thru 4/17/2016)	$	49,500.00
Premera Blue Cross	$	3,250.00
Tricare (Claim file Password Protected)		
United Health Group (Optum)	$	481,341.91
WellCare Health Plans, Inc.	$	1,095.00
XL Health	$	76.00
Total	**$**	**1,339,180.04**

Figure 15 - Unpaid claims analysis

7. Unpaid Claims were identified in the Claims data. After excluding the CPT codes considered "suspect" and excluding Duplicate Claims, Claims that were submitted but not paid were identified. For all Claims files the total amount of unpaid Claims is **$1,339,180.04**. This total is the sum obtained from all insurers. Each claim file was

examined and claims with non-suspect" CPT codes were identified. Any duplicate claims were eliminated. A total of unpaid claims for each insurer was found by identifying the remaining claims that were billed but not paid.

The Unpaid Claims by insurer:

As previously noted some claims files only contain the CPT codes under investigation, these files do not contain the correctly billed data from that insurer. There may be unpaid claims that have been excluded by not including all CPT codes in the claims data. The Unpaid claims total is underestimated because of the omission of correctly billed claims.

8. Detailed claim analysis was performed on four individuals.

a. The patient J. Hattrup was interviewed on 4/11/14 regarding his heart monitoring in 2011. He remembers wearing a heart monitor. He also remembers visiting a neurologist for testing at some point in time which was not specified.

The United Health Care claims for the patient Hattrup were identified. The dates of Service listed on the claims are 4/11/11, 4/12/11, 4/15/11, 4/18/11 and 4/21/11.

Claim History from United Health Group for J.Hattrup

PAT_L_NAME	PAT_F_NAME	DOS_BEGIN	CLAIM	LINE	DX1	DX1_DESCR	CPT	CPT_DESCR	UNITS	AMTCHG	AMTPAID	Valid Per US
HATTRUP	JOHN	4/11/11	283578669201	1	78650	CHEST PAIN (	93226	ECG MONITC	1	$ 325.00	$ 325.00	Yes
HATTRUP	JOHN	4/11/11	283578669201	3	78650	CHEST PAIN (	93799	CARDIOVASC	1	$ 325.00	$ 325.00	Yes
HATTRUP	JOHN	4/11/11	283578669201	2	78650	CHEST PAIN (	95827	EEG, ALL NIG	1	$ 325.00	$ 325.00	
HATTRUP	JOHN	4/11/11	283578669201	1	78650	CHEST PAIN (	J8499	PRSC RX ORA	1	$ 0.01	$ -	
HATTRUP	JOHN	4/12/11	285937578601	1	78650	CHEST PAIN (	93271	ECG/MONIT(	1	$ 695.00	$ 695.00	
HATTRUP	JOHN	4/12/11	285937578601	1	78650	CHEST PAIN (	J8499	PRSC RX ORA	1	$ 0.01	$ -	
HATTRUP	JOHN	4/15/11	288563029501	1	78650	CHEST PAIN (	93226	ECG MONITC	1	$ 295.00	$ 295.00	
HATTRUP	JOHN	4/15/11	288563029501	2	78650	CHEST PAIN (	95827	EEG, ALL NIG	1	$ 400.00	$ 400.00	
HATTRUP	JOHN	4/15/11	288563029501	3	78650	CHEST PAIN (	95921	AUTONOMIC	1	$ 225.00	$ 225.00	
HATTRUP	JOHN	4/15/11	288563029501	1	78650	CHEST PAIN (	J8499	PRSC RX ORA	1	$ 0.01	$ -	
HATTRUP	JOHN	4/18/11	291903650901	3	78650	CHEST PAIN (	93025	MICROVOLT	1	$ 325.00	$ 325.00	
HATTRUP	JOHN	4/18/11	291903650901	1	78650	CHEST PAIN (	93226	ECG MONITC	1	$ 300.00	$ 300.00	
HATTRUP	JOHN	4/18/11	291903650901	2	78650	CHEST PAIN (	95827	EEG, ALL NIG	1	$ 325.00	$ 325.00	
HATTRUP	JOHN	4/18/11	291903650901	1	78650	CHEST PAIN (	J8499	PRSC RX ORA	1	$ 0.01	$ -	
HATTRUP	JOHN	4/21/11	291903650801	3	78650	CHEST PAIN (	93025	MICROVOLT	1	$ 325.00	$ 325.00	
HATTRUP	JOHN	4/21/11	291903650801	1	78650	CHEST PAIN (	93226	ECG MONITC	1	$ 300.00	$ -	
HATTRUP	JOHN	4/21/11	291903650801	2	78650	CHEST PAIN (	95827	EEG, ALL NIG	1	$ 325.00	$ 325.00	
HATTRUP	JOHN	4/21/11	291903650801	1	78650	CHEST PAIN (	J8499	PRSC RX ORA	1	$ 0.01	$ -	
										$ 4,490.05	$ 4,190.00	

Figure 16 - Summary of Hattrup Claims Analysis

b. The patient S.R. Foster (Sixtos) was interviewed on 4/14/14 regarding her heart monitoring. She remembers wearing a cardiac monitor for approximately two weeks during her pregnancy in 2008/2009. She could not recall wearing a cardiac monitor in 2011. The Cigna claims for Foster include 4 dates of service: 8/10/11, 8/11/11, 8/18/11 and 8/24/11.

Claim History from Cigna for Foster (Sixtos)

Member Last	Member Firs	Member Nur	First Service	Procedure Code	DESCRIPTION	Charge Amou	Eligible Char	Paid Amount	Valid per US
FOSTER	STACEY	5699150860	8/10/11	93226	"ECG MONITOR/REPORT, 24 HRS"	100.00	60.00	0.00	Yes
FOSTER	STACEY	5699150860	8/10/11	93799	CARDIOVASCULAR PROCEDURE	325.00	325.00	0.00	Yes
FOSTER	STACEY	5699150860	8/10/11	95827	NIGHT ELECTROENCEPHALOGRAM	325.00	195.00	0.00	
FOSTER	STACEY	5699150860	8/11/11	93271	ECG/MONITORING AND ANALYSIS	695.00	417.00	250.20	
FOSTER	STACEY	5699150860	8/18/11	93226	"ECG MONITOR/REPORT, 24 HRS"	195.00	117.00	0.00	
FOSTER	STACEY	5699150860	8/18/11	95827	NIGHT ELECTROENCEPHALOGRAM	400.00	240.00	112.20	
FOSTER	STACEY	5699150860	8/18/11	95921	AUTONOMIC NERV FUNCTION TEST	225.00	135.00	81.00	
FOSTER	STACEY	5699150860	8/24/11	93025	MICROVOLT T-WAVE ASSESS	325.00	195.00	117.00	
FOSTER	STACEY	5699150860	8/24/11	93226	"ECG MONITOR/REPORT, 24 HRS"	195.00	117.00	70.20	
FOSTER	STACEY	5699150860	8/24/11	95827	NIGHT ELECTROENCEPHALOGRAM	325.00	195.00	117.00	
						3,110.00		747.60	

c. The patient M. Bennett was interviewed on 4/14/14 regarding her cardiac monitoring. She remembered wearing a cardiac monitor but could not recall the date. It was placed on at her physician's office on a Friday and she took it off on Sunday and returned it to her physician's office on Monday. She recalls wearing the device while she slept.

The United Health Care claims for M. Bennett include four dates of service: 12/2/12, 12/4/12, 12/6/12 and 12/10/12.

Claim History from United Health Group for M. Bennett

PAT_L_NAME	PAT_F_NAME	DOS_BEGIN	CLAIM	LINE	DX1	DX1_DESCR	DX2	CPT	CPT_DESCR	UNITS	AMTCHG	AMTPAID	Valid Per US
BENNETT	MARTHA	12/3/12	395307288601	1	7851	PALPITATION		93226	ECG MONITC	1	$ 195.00	$ 96.53	Yes
BENNETT	MARTHA	12/3/12	395307288601	3	7851	PALPITATION		93799	CARDIOVASC	1	$ 195.00	$ 96.53	Yes
BENNETT	MARTHA	12/3/12	395307288601	2	7851	PALPITATION		95827	EEG, ALL NIG	1	$ 325.00	$ 160.88	
BENNETT	MARTHA	12/3/12	395307288601	1	7851	PALPITATION		J8499	PRSC RX ORA	1	$ 0.01	$ -	
BENNETT	MARTHA	12/4/12	399402695101	2	7851	PALPITATION		93025	MICROVOLT	1	$ 395.00	$ 213.30	
BENNETT	MARTHA	12/4/12	399402695101	1	7851	PALPITATION		93271	ECG/MONITO	1	$ 595.00	$ 321.30	
BENNETT	MARTHA	12/6/12	398955221801	3	7851	PALPITATION		93025	MICROVOLT	1	$ 325.00	$ -	
BENNETT	MARTHA	12/6/12	398955221801	1	7851	PALPITATION		93226	ECG MONITC	1	$ 195.00	$ -	
BENNETT	MARTHA	12/6/12	398955221801	2	7851	PALPITATION		95827	EEG, ALL NIG	1	$ 325.00	$ -	
BENNETT	MARTHA	12/10/12	402261643201	1	7851	PALPITATION		93226	ECG MONITC	1	$ 100.00	$ -	
BENNETT	MARTHA	12/10/12	402261643201	3	7851	PALPITATION		95806	SLEEP STUDY	1	$ 395.00	$ 195.53	
BENNETT	MARTHA	12/10/12	402261643201	2	7851	PALPITATION		95827	EEG, ALL NIG	1	$ 400.00	$ 198.00	
											$ 3,445.01	$ 1,282.07	

d. The patient L Solmor was interviewed on 4/14/14 regarding her cardiac monitoring. She recalled wearing the monitor and estimated the date to be around June 2013. She stated she wore it for 24 hours and followed up with a cardiologist 6 months later. The Aetna claims for L Solmor include two dates of service: 5/29/13 and 5/30/13.

Claim History from Aetna

LAST_NM	FIRST_NM	SERVICE_DT	PRCDR_CD	MOD	PRCDR_CD_TEXT	BILLED AMT	PAID AMT	Valid Per US
SOLMOR	LISA	5/29/13	93226		ECG MONIT/REPRT UP TO 48 HRS	$100.00	$55.00	Yes
SOLMOR	LISA	5/29/13	93799	TC	CARDIOVASCULAR PROCEDURE	$195.00	$107.25	Yes
SOLMOR	LISA	5/29/13	95827		NIGHT ELECTROENCEPHALOGRAN	$325.00	$133.75	
SOLMOR	LISA	5/30/13	93025		MICROVOLT T-WAVE ASSESS	$395.00	$0.00	
SOLMOR	LISA	5/30/13	93271		ECG/MONITORING AND ANALYSIS	$395.00	$0.00	
						$1,410.00	$296.00	

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Exhibit C – Test Results

Mathematical Errors in Government Presentencing Information Report

The government presented a list of Counts 1- 14 for fraud. I analyzed the counts, added up the totals and compared them to my own calculations which included a review of each and every claim. The presentencing report appears to rely on other calculations I do not have that may have been performed by the FBI or others and then given to the author of the PIR / PSR. Paragraph 20 of the PSR states, "

Information pertaining to the offense was obtained from the Indictment, the trial memoranda, and materials provided by the United States Attorney's office." The government's error rate was 6% to 26% as follows:

CONTINUED NEXT PAGE

Count 1 charges that on April 18, 2011, Mirando caused a $325 false claim to be submitted to UnitedHealthcare (United) for services purportedly provided to beneficiary J.H. on April 11, 2011, in violation of 18 U.S.C. §§ 1347, 2(b).	$ 325.00	
Count 2 charges that on May 16, 2011, Mirando caused a $695 false claim to be submitted to United for services purportedly provided to beneficiary J.H. on April 12, 2011, in violation of 18 U.S.C. §§ 1347, 2(b).	$ 695.00	
Count 3 charges that on June 13, 2011, Mirando caused a $695 false claim to be submitted to United for services purportedly provided to beneficiary J.H. on April 15, 2011, in violation of 18 U.S.C. §§ 1347, 2(b).	$ 695.00	
Count 4 charges that on July 18, 2011, Mirando caused a $950 false claim to be submitted to United for services purportedly provided to beneficiary J.H. on April 18, 2011, in violation of 18 U.S.C. §§ 1347, 2(b).	$ 950.00	
Count 5 charges that on July 18, 2011, Mirando caused a $950 false claim to be submitted to United for services purportedly provided to beneficiary J.H. on April 21, 2011, in violation of 18 U.S.C. §§ 1347, 2(b).	$ 950.00	
Subtotal Beneficiary J.H.		**$ 3,615.00**
Count 7 charges that on November 22, 2011, Mirando caused a $695 false claim to be submitted to Cigna for services purportedly provided to beneficiary S.F. on August 11, 2011, in violation of 18 U.S.C. §§ 1347, 2(b).	$ 695.00	
Count 8 charges that on November 22, 2011, Mirando caused a $595 false claim to be submitted to Cigna for services purportedly provided to beneficiary S.F. on August 18, 2011, in violation of 18 U.S.C. §§ 1347, 2(b).	$ 595.00	
Count 9 charges that on December 15, 2011, Mirando caused an $845 false claim to be submitted to Cigna for services purportedly provided to beneficiary S.F. on August 24, 2011, in violation of 18 U.S.C. §§ 1347, 2(b).	$ 845.00	
Subtotal Beneficiary S.F.		**$ 2,135.00**
Count 10 charges that on December 10, 2012, Mirando caused a $325 false claim to be submitted to United for services purportedly provided to beneficiary M.B. on December 3, 2012, in violation of 18 U.S.C. §§ 1347, 2(b).	$ 325.00	
Count 11 charges that on January 11, 2013, Mirando caused a $990 false claim to be submitted to United for services purportedly provided to beneficiary M.B. on December 4, 2012, in violation of 18 U.S.C. §§ 1347, 2(b).	$ 990.00	
Count 12 charges that on January 11, 2013, Mirando caused an $845 false claim to be submitted to United for services purportedly provided to beneficiary M.B. on December 6, 2012, in violation of 18 U.S.C. §§ 1347, 2(b).	$ 845.00	
Count 13 charges that on February 6, 2013, Mirando caused an $895 false claim to be submitted to United for services purportedly provided to beneficiary M.B. on December 10, 2012, in violation of 18 U.S.C. §§ 1347, 2(b).	$ 895.00	
Subtotal Beneficiary M.B.		**$ 3,055.00**
Count 14 charges that on June 6, 2013, Mirando caused a $325 false claim to be submitted to Aetna for services purportedly provided to beneficiary L.S. on May 29, 2013, in violation of 18 U.S.C. §§ 1347, 2(b).	$ 325.00	
Count 15 charges that on July 9, 2013, Mirando caused a $790 false claim to be submitted to Aetna for services purportedly provided to beneficiary L.S. on May 30, 2013, in violation of 18 U.S.C. §§ 1347, 2(b).	$ 790.00	
Subtotal Beneficiary L.S.		**$ 1,115.00**

Figure 17 - Analysis of PSR / PIR Counts 1-15 of Fraud

Next I compared the totals with those from my independent analysis:

Government Fraud Counts vs. Arrigo Calculations							
	Government				Arrigo Analysis		
	Presentencing Info. Report	No of Claims Analyzed for Each Insured	Difference	Governmen t Error Rate	Total Billed	Total Paid	Gov.: No of Claims by Analyzed by
Hattrup	$ 3,615.00	69	-$ 225.05	-6%	$ 3,840.05	$ 3,540.00	69
Foster (Sixtos)	$ 2,135.00	12	-$ 550.00	-26%	$ 2,685.00	$ 747.60	12
Bennett	$ 3,055.00	49		0%	$ 3,055.01	$ 1,089.01	49
Solmor	$ 1,115.00	7		0%	$ 1,115.00	$ 133.75	7
Total	$ 9,920.00	137	-$ 775.06	-8%	$ 10,695.06	$ 5,510.36	137
Total Claims in Data Produced by Government							**31,760**

Figure 18 - Comparison of Government Fraud Counts vs. Arrigo Analysis.

This analysis with respect to "Arrigo Analysis" columns was developed by evaluating each of the 137 claims as follows:

Claims were evaluated based on the Government's criteria of 'suspect,' unable to perform and duplicate and checked for assumptions.

Insured Hattrup's data is as follows which ties to my analysis and differs from the Government's analysis:

CONTINUED NEXT PAGE

Claim History from United Health Group for J.Hattrup

PAT_L_NAME	PAT_F_NAME	DOS_BEGIN	CLAIM	LINE	DX1	DX1_DESCR	CPT	CPT_DESCR	UNITS	AMTCHG	AMTPAID	Valid Per US
HATTRUP	JOHN	4/11/11	283578669201	1	78650	CHEST PAIN (	93226	ECG MONITOR/REPORT, 24 HRS	-1	$ 325.00	$ -	
HATTRUP	JOHN	4/11/11	283578669201	1	78650	CHEST PAIN (	93226	ECG MONITOR/REPORT, 24 HRS	1	$ 325.00	$ -	
HATTRUP	JOHN	4/11/11	283578669201	1	78650	CHEST PAIN (	93226	ECG MONITOR/REPORT, 24 HRS	1	$ 325.00	$ 325.00	Yes
HATTRUP	JOHN	4/11/11	283578669201	3	78650	CHEST PAIN	93799	CARDIOVASCULAR PROCEDURE	1	$ 325.00	$ -	
HATTRUP	JOHN	4/11/11	283578669201	3	78650	CHEST PAIN	93799	CARDIOVASCULAR PROCEDURE	-1	-$ 325.00	$ -	
HATTRUP	JOHN	4/11/11	283578669201	3	78650	CHEST PAIN	93799	CARDIOVASCULAR PROCEDURE	1	$ 325.00	$ 325.00	Yes
HATTRUP	JOHN	4/11/11	283578669201	2	78650	CHEST PAIN (	95827	EEG, ALL NIGHT RECORDING	-1	-$ 325.00	$ -	
HATTRUP	JOHN	4/11/11	283578669201	2	78650	CHEST PAIN (	95827	EEG, ALL NIGHT RECORDING	1	$ 325.00	$ -	
HATTRUP	JOHN	4/11/11	283578669201	2	78650	CHEST PAIN (	95827	EEG, ALL NIGHT RECORDING	1	$ 325.00	$ 325.00	
HATTRUP	JOHN	4/11/11	283578669201	1	78650	CHEST PAIN	J8499	PRSC RX ORAL NONCHEMOTHAPEUT	1	$ 0.01	$ -	
HATTRUP	JOHN	4/12/11	285937578601	1	78650	CHEST PAIN (	93271	ECG/MONITORING AND ANALYSIS	1	$ 695.00	$ -	
HATTRUP	JOHN	4/12/11	285937578601	1	78650	CHEST PAIN (	93271	ECG/MONITORING AND ANALYSIS	-1	-$ 695.00	$ -	
HATTRUP	JOHN	4/12/11	285937578601	1	78650	CHEST PAIN (	93271	ECG/MONITORING AND ANALYSIS	1	$ 695.00	$ 695.00	
HATTRUP	JOHN	4/12/11	285937578601	1	78650	CHEST PAIN	J8499	PRSC RX ORAL NONCHEMOTHAPEUT	1	$ 0.01	$ -	
HATTRUP	JOHN	4/15/11	288563029501	1	78650	CHEST PAIN (	93226	ECG MONITOR/REPORT, 24 HRS	-1	-$ 295.00	$ -	
HATTRUP	JOHN	4/15/11	288563029501	1	78650	CHEST PAIN (	93226	ECG MONITOR/REPORT, 24 HRS	1	$ 295.00	$ -	
HATTRUP	JOHN	4/15/11	288563029501	1	78650	CHEST PAIN (	93226	ECG MONITOR/REPORT, 24 HRS	1	$ 295.00	$ 295.00	
HATTRUP	JOHN	4/15/11	288563029501	2	78650	CHEST PAIN (	95827	EEG, ALL NIGHT RECORDING	1	$ 400.00	$ -	
HATTRUP	JOHN	4/15/11	288563029501	2	78650	CHEST PAIN (	95827	EEG, ALL NIGHT RECORDING	-1	-$ 400.00	$ -	
HATTRUP	JOHN	4/15/11	288563029501	2	78650	CHEST PAIN (	95827	EEG, ALL NIGHT RECORDING	1	$ 400.00	$ 400.00	
HATTRUP	JOHN	4/15/11	288563029501	3	78650	CHEST PAIN	95921	AUTONOMIC NERV FUNCTION TEST	1	$ 225.00	$ -	
HATTRUP	JOHN	4/15/11	288563029501	3	78650	CHEST PAIN	95921	AUTONOMIC NERV FUNCTION TEST	-1	-$ 225.00	$ -	
HATTRUP	JOHN	4/15/11	288563029501	3	78650	CHEST PAIN	95921	AUTONOMIC NERV FUNCTION TEST	1	$ 225.00	$ 225.00	
HATTRUP	JOHN	4/15/11	288563029501	1	78650	CHEST PAIN	J8499	PRSC RX ORAL NONCHEMOTHAPEUT	1	$ 0.01	$ -	
HATTRUP	JOHN	4/18/11	291903650901	3	78650	CHEST PAIN (	93025	MICROVOLT T-WAVE ASSESS	-1	-$ 325.00	$ -	
HATTRUP	JOHN	4/18/11	291903650901	3	78650	CHEST PAIN (	93025	MICROVOLT T-WAVE ASSESS	1	$ 325.00	$ -	
HATTRUP	JOHN	4/18/11	291903650901	3	78650	CHEST PAIN (	93025	MICROVOLT T-WAVE ASSESS	1	$ 325.00	$ 325.00	
HATTRUP	JOHN	4/18/11	291903650901	1	78650	CHEST PAIN (	93226	ECG MONITOR/REPORT, 24 HRS	-1	-$ 300.00	$ -	
HATTRUP	JOHN	4/18/11	291903650901	1	78650	CHEST PAIN (	93226	ECG MONITOR/REPORT, 24 HRS	1	$ 300.00	$ -	
HATTRUP	JOHN	4/18/11	291903650901	1	78650	CHEST PAIN (	93226	ECG MONITOR/REPORT, 24 HRS	1	$ 300.00	$ 300.00	
HATTRUP	JOHN	4/18/11	291903650901	2	78650	CHEST PAIN (	95827	EEG, ALL NIGHT RECORDING	1	$ 325.00	$ -	
HATTRUP	JOHN	4/18/11	291903650901	2	78650	CHEST PAIN (	95827	EEG, ALL NIGHT RECORDING	-1	-$ 325.00	$ -	
HATTRUP	JOHN	4/18/11	291903650901	2	78650	CHEST PAIN (	95827	EEG, ALL NIGHT RECORDING	1	$ 325.00	$ 325.00	
HATTRUP	JOHN	4/18/11	291903650901	1	78650	CHEST PAIN	J8499	PRSC RX ORAL NONCHEMOTHAPEUT	1	$ 0.01	$ -	
HATTRUP	JOHN	4/21/11	291903650801	3	78650	CHEST PAIN (	93025	MICROVOLT T-WAVE ASSESS	1	$ 325.00	$ -	
HATTRUP	JOHN	4/21/11	291903650801	3	78650	CHEST PAIN (	93025	MICROVOLT T-WAVE ASSESS	-1	-$ 325.00	$ -	
HATTRUP	JOHN	4/21/11	291903650801	3	78650	CHEST PAIN (	93025	MICROVOLT T-WAVE ASSESS	1	$ 325.00	$ 325.00	
HATTRUP	JOHN	4/21/11	291903650801	1	78650	CHEST PAIN (	93226	ECG MONITOR/REPORT, 24 HRS	-1	-$ 300.00	$ -	
HATTRUP	JOHN	4/21/11	291903650801	1	78650	CHEST PAIN (	93226	ECG MONITOR/REPORT, 24 HRS	1	$ 300.00	$ 300.00	
HATTRUP	JOHN	4/21/11	291903650801	1	78650	CHEST PAIN (	93226	ECG MONITOR/REPORT, 24 HRS	1	$ 300.00	$ -	
HATTRUP	JOHN	4/21/11	291903650801	2	78650	CHEST PAIN (	95827	EEG, ALL NIGHT RECORDING	-1	-$ 325.00	$ -	
HATTRUP	JOHN	4/21/11	291903650801	2	78650	CHEST PAIN (	95827	EEG, ALL NIGHT RECORDING	1	$ 325.00	$ -	
HATTRUP	JOHN	4/21/11	291903650801	2	78650	CHEST PAIN (	95827	EEG, ALL NIGHT RECORDING	1	$ 325.00	$ 325.00	
HATTRUP	JOHN	4/21/11	291903650801	1	78650	CHEST PAIN	J8499	PRSC RX ORAL NONCHEMOTHAPEUT	1	$ 0.01	$ -	
										$ 4,490.05	$ 4,490.00	

Claim History from United Health Group for J.Hattrup

PAT_L_NAME	PAT_F_NAME	DOS_BEGIN	CLAIM	LINE	DX1	DX1_DESCR	CPT	CPT_DESCR	UNITS	AMTCHG	AMTPAID	Valid Per US
HATTRUP	JOHN	4/11/11	283578669201	1	78650	CHEST PAIN (	93226	ECG MONITOR/REPORT, 24 HRS	1	$ 325.00	$ 325.00	Yes
HATTRUP	JOHN	4/11/11	283578669201	3	78650	CHEST PAIN	93799	CARDIOVASCULAR PROCEDURE	1	$ 325.00	$ 325.00	Yes
HATTRUP	JOHN	4/11/11	283578669201	2	78650	CHEST PAIN (	95827	EEG, ALL NIGHT RECORDING	1	$ 325.00	$ 325.00	
HATTRUP	JOHN	4/11/11	283578669201	1	78650	CHEST PAIN	J8499	PRSC RX ORAL NONCHEMOTHAPEUT	1	$ 0.01	$ -	
HATTRUP	JOHN	4/12/11	285937578601	1	78650	CHEST PAIN (	93271	ECG/MONITORING AND ANALYSIS	1	$ 695.00	$ 695.00	
HATTRUP	JOHN	4/12/11	285937578601	1	78650	CHEST PAIN	J8499	PRSC RX ORAL NONCHEMOTHAPEUT	1	$ 0.01	$ -	
HATTRUP	JOHN	4/15/11	288563029501	1	78650	CHEST PAIN (	93226	ECG MONITOR/REPORT, 24 HRS	1	$ 295.00	$ 295.00	
HATTRUP	JOHN	4/15/11	288563029501	2	78650	CHEST PAIN (	95827	EEG, ALL NIGHT RECORDING	1	$ 400.00	$ 400.00	
HATTRUP	JOHN	4/15/11	288563029501	3	78650	CHEST PAIN	95921	AUTONOMIC NERV FUNCTION TEST	1	$ 225.00	$ 225.00	
HATTRUP	JOHN	4/15/11	288563029501	1	78650	CHEST PAIN	J8499	PRSC RX ORAL NONCHEMOTHAPEUT	1	$ 0.01	$ -	
HATTRUP	JOHN	4/18/11	291903650901	3	78650	CHEST PAIN (	93025	MICROVOLT T-WAVE ASSESS	1	$ 325.00	$ 325.00	
HATTRUP	JOHN	4/18/11	291903650901	1	78650	CHEST PAIN (	93226	ECG MONITOR/REPORT, 24 HRS	1	$ 300.00	$ 300.00	
HATTRUP	JOHN	4/18/11	291903650901	2	78650	CHEST PAIN (	95827	EEG, ALL NIGHT RECORDING	1	$ 325.00	$ 325.00	
HATTRUP	JOHN	4/18/11	291903650901	1	78650	CHEST PAIN	J8499	PRSC RX ORAL NONCHEMOTHAPEUT	1	$ 0.01	$ -	
HATTRUP	JOHN	4/21/11	291903650801	3	78650	CHEST PAIN (	93025	MICROVOLT T-WAVE ASSESS	1	$ 325.00	$ 325.00	
HATTRUP	JOHN	4/21/11	291903650801	1	78650	CHEST PAIN (	93226	ECG MONITOR/REPORT, 24 HRS	1	$ 300.00	$ -	
HATTRUP	JOHN	4/21/11	291903650801	2	78650	CHEST PAIN (	95827	EEG, ALL NIGHT RECORDING	1	$ 325.00	$ 325.00	
HATTRUP	JOHN	4/21/11	291903650801	1	78650	CHEST PAIN	J8499	PRSC RX ORAL NONCHEMOTHAPEUT	1	$ 0.01	$ -	
										$ 4,490.05	$ 4,190.00	
								Alleged Fraud (Total - Valid)		$ 3,840.05	$ 3,540.00	

Figure 19 - Supporting detail of Hattrup claims analysis (L.H.) vs. PSR Count analysis

I performed the same analysis for patient / insured Foster (Sixtos)

Member Last	Member First	Member Nur	First Service	Procedure Code	DESCRIPTION	Charge Amo	Eligible Char	Paid Amoun	Valid per US
FOSTER	STACEY	5699150860	8/10/11	93226	"ECG MONITOR/REPORT, 24 HRS"	$ 100.00	$ 60.00	$ -	Yes
FOSTER	STACEY	5699150860	8/10/11	93799	CARDIOVASCULAR PROCEDURE	$ 325.00	$ 325.00	$ -	Yes
FOSTER	STACEY	5699150860	8/10/11	95827	NIGHT ELECTROENCEPHALOGRAM	$ 325.00	$ 195.00	$ -	
FOSTER	STACEY	5699150860	8/11/11	93271	ECG/MONITORING AND ANALYSIS	$ 695.00	$ 417.00	$ 250.20	
FOSTER	STACEY	5699150860	8/18/11	93226	"ECG MONITOR/REPORT, 24 HRS"	$ 195.00	$ 117.00	$ -	
FOSTER	STACEY	5699150860	8/18/11	95827	NIGHT ELECTROENCEPHALOGRAM	$ 400.00	$ 240.00	$ 112.20	
FOSTER	STACEY	5699150860	8/18/11	95921	AUTONOMIC NERV FUNCTION TEST	$ 225.00	$ 135.00	$ 81.00	
FOSTER	STACEY	5699150860	8/24/11	93025	MICROVOLT T-WAVE ASSESS	$ 325.00	$ 195.00	$ 117.00	
FOSTER	STACEY	5699150860	8/24/11	93226	"ECG MONITOR/REPORT, 24 HRS"	$ 195.00	$ 117.00	$ 70.20	
FOSTER	STACEY	5699150860	8/24/11	95827	NIGHT ELECTROENCEPHALOGRAM	$ 325.00	$ 195.00	$ 117.00	
					Totals	$ 3,110.00		$ 747.60	
					Alleged Fraud (Total - Valid)	$ 2,685.00		$ 747.60	

Figure 20 - Supporting detail of analysis of claims for Foster (Sixtos)

Next, I performed the same analysis for patient / insured Bennett

DX1	DX1_DESCR	DX2	CPT	CPT_DESCR	UNITS	AMTCHG	AMTPAID	Valid Per US
7851	PALPITATION		93226	ECG MONITOR/REPORT, 24 HRS	1	$ 195.00	$ 96.53	Yes
7851	PALPITATION		93799	CARDIOVASCULAR PROCEDURE	1	$ 195.00	$ 96.53	Yes
7851	PALPITATION		95827	EEG, ALL NIGHT RECORDING	1	$ 325.00	$ 160.88	
7851	PALPITATION		J8499	PRSC RX ORAL NONCHEMOTHAPEUTIC I	1	$ 0.01	$ -	
7851	PALPITATION		93025	MICROVOLT T-WAVE ASSESS	1	$ 395.00	$ 213.30	
7851	PALPITATION		93271	ECG/MONITORING AND ANALYSIS	1	$ 595.00	$ 321.30	
7851	PALPITATION		93025	MICROVOLT T-WAVE ASSESS	1	$ 325.00	$ -	
7851	PALPITATION		93226	ECG MONITOR/REPORT, 24 HRS	1	$ 195.00	$ -	
7851	PALPITATION		95827	EEG, ALL NIGHT RECORDING	1	$ 325.00	$ -	
7851	PALPITATION		93226	ECG MONITOR/REPORT, 24 HRS	1	$ 100.00	$ -	
7851	PALPITATION		95806	SLEEP STUDY UNATT&RESP EFFT	1	$ 395.00	$ 195.53	
7851	PALPITATION		95827	EEG, ALL NIGHT RECORDING	1	$ 400.00	$ 198.00	
				Total		$ 3,445.01	$ 1,282.07	
				Alleged Fraud (Total - Valid)		$ 3,055.01	$ 1,089.01	

Figure 21 - Supporting detail of Bennett claims analysis vs. PSR Count analysis

Finally I performed the same analysis for patient / insured Solmor:

Claim History from Aetna								
LAST_NM	FIRST_NM	SERVICE_DT	PRCDR_CD	MOD	PRCDR_CD_TEXT	BILLED AMT	PAID AMT	Valid Per US
SOLMOR	LISA	5/29/13	93226		ECG MONIT/REPRT UP TO 48 HRS	$ 100.00	$ 55.00	Yes
SOLMOR	LISA	5/29/13	93799	TC	CARDIOVASCULAR PROCEDURE	$ 195.00	$ 107.25	Yes
SOLMOR	LISA	5/29/13	95827		NIGHT ELECTROENCEPHALOGRAM	$ 325.00	$ 133.75	
SOLMOR	LISA	5/30/13	93025		MICROVOLT T-WAVE ASSESS	$ 395.00	$ -	
SOLMOR	LISA	5/30/13	93271		ECG/MONITORING AND ANALYSIS	$ 395.00	$ -	
					Total	$ 1,410.00	$ 296.00	
					Alleged Fraud (Total - Valid)	$ 1,115.00	$ 133.75	

Figure 22 - Supporting detail of patient Solmor vs. PSR Count analysis

Billed vs. Intended vs. Actual / Foreseeable Loss for "unable to perform" procedures

As noted earlier I found flaws and statistically invalid methods in the governments methodologies regarding 'unable to perform' for reasons:

1. The presumption that all procedures were performed with a device that was unable to perform the procedure based on the frequency as attested by a government witness was wrong when compared to FDA filings.
2. The presumption that all procedures billed in the classification of 'unable to perform' were actually provided using the Datrix device in question, without any documentation proving conclusively that this device as used
3. A high error rate statistically invalid method yielding only 19% confidence based on a limited sample size.
4. In addition, there were mathematical errors in the totals even if one accepts the Governments logic in items 1-3 above. I determined arithmetic errors by dong the following:

All codes from all payors were analyzed and summed to arrive at the following findings:

5. Of the accurately totaled $7.470 million in billings, the intended loss is $2.3 million using the Governments' methodology, times the payment to charge ratio for Holter Labs business of 31%. Actual loss is $2.575 million using correct totals for the actual amount paid.
6. Because of a below industry standard 19% level of certainty it cannot be concluded what the intended loss or actual loss are.

	Suspect CPT Codes			
Insurance Company	Billed	Intended Loss	Paid (Actual Loss)	Statistically Valid Conculsion
Aetna Life Insurance Company	$ 1,187,835.00	$ 368,228.85	$ 307,309.96	$ -
Anthem Inc/ Anthem Blue Cross/Wellpoint	$ 1,490,910.00	$ 462,182.10	$ 368,700.63	$ -
Blue Cross Blue Shield of Alabama	$ 176,839.00	$ 54,820.09	$ 101,583.69	$ -
BCBS of Arkansas (Claim file Password Protected)				$ -
Blue Cross Blue Shield of Florida	$ 17,201.00	$ 5,332.31	$ 4,670.53	$ -
Blue Cross Blue Shield of Hawaii	$ 1,920.00	$ 595.20	$ 1,212.51	$ -
Blue Cross Blue Shield of Minnesota	$ 13,545.00	$ 4,198.95	$ 8,402.24	$ -
Blue Cross Blue Shield of New Jersey	$ 19,555.00	$ 6,062.05	$ 8,554.98	$ -
Blue Cross & Blue Shiled of Rhode Island	$ 14,485.00	$ 4,490.35	$ 8,428.15	$ -
Blue Cross Blue Shield of South Carolina	$ 68,558.00	$ 21,252.98	$ 30,952.36	$ -
Cigna	$ 556,131.00	$ 172,400.61	$ 186,763.32	$ -
Coventry Health Care	$ 13,297.00	$ 4,122.07	$ 5,935.40	$ -
Emblem Health	$ 36,645.98	$ 11,360.25	$ 7,814.00	$ -
GEHA	$ 25,866.00	$ 8,018.46	$ 11,053.67	$ -
Healthfirst	$ 13,890.00	$ 4,305.90	$ 31.50	$ -
Highmark Blue Cross	$ 384,667.00	$ 119,246.77	$ 182,721.89	$ -
Humana	$ 542,001.50	$ 168,020.47	$ 213,050.69	$ -
IHC Health Solutions	$ 325.00	$ 100.75	$ -	$ -
Independence Blue Cross	$ 126,336.00	$ 39,164.16	$ 64,539.31	$ -
Independent Health	$ 125,465.00	$ 38,894.15	$ 99,430.07	$ -
Kaiser Permanente	$ 3,875.00	$ 1,201.25	$ 2,758.55	$ -
Premera Blue Cross	$ 20,770.00	$ 6,438.70	$ 7,003.28	$ -
Tricare (Claim file Password Protected)		$ -		$ -
United Health Group (Optum)	$ 2,611,469.74	$ 809,555.62	$ 942,251.86	$ -
WellCare Health Plans, Inc.	$ 9,150.00	$ 2,836.50	$ 5,756.57	$ -
XL Health	$ 9,622.50	$ 2,982.98	$ 6,015.31	$ -
				$ -
Total	**$ 7,470,359.72**	$ 2,315,811.51	**$ 2,574,940.47**	$ -

Figure 23 - Billed vs. Intended vs. Paid

Billed vs. Intended vs. Actual / Foreseeable Loss for "Duplicates"

As noted earlier I found flaws in the assumptions regarding what constitutes a fraudulent duplicate vs. a re-billed claim or a duplicate of a portion of a claim that may be payable. Evaluating the Government's methodology to determine the mathematically correct value for 'duplicates" I evaluated every claim for all payors. The results were as follows:

Observations:

- Mr. Mirando does not determine the clinical necessity of the services he provides, it is the responsibility of the physician to decide what specific study or studies are needed for the patient's specific condition. In other words, Holter Labs is in the business of providing services that are ordered by physicians.
- Mr. Mirando should not bill for any studies other than those requested by the clinician. It is up to the clinician to document the evidence for the medical necessity of the study. It is not up to Mr. Mirando to determine the medical necessity of the study performed assuming it was requested by the clinician.
- To prove fraud, records would need to be provided showing that services were performed that were either:
    - Not ordered by a physician
    - Ordered by a physician but not medically necessary. In this case, the fraud would be committed by the physician who ordered the services that Holter Labs provides. Of approximately 150,000 dates of service over several years I was provided with less than ten (10) complete records of physician orders for specific patients. Even in those cases is not clear what device was used to perform the procedure.
- Mr. Mirando is not a clinician and not trained to clinically interpret measures of cardiac electrical activity, EEGs, vagal responses, sleep disorders or other interpretations of the reports generated for clinicians who use his services.
- Mr. Mirando provides his clients (generally primary care physicians) with cardiac monitor devices that are used by the client as part of cardiac related evaluations that are deemed medically necessary by the physician.
- Mr. Mirando does not provide diagnostic interpretation but only the equipment and reported data derived from the equipment.
- Mr. Mirando does not provide any physical testing or evaluation of the patient directly.
- Non-coverage of services various greatly from one payer to the next. Non-coverage or denial does not imply fraud. Submission of a duplicate claim also does not imply fraud in and of itself unless there is evidence that multiple claims with different IDs where submitted for the same type of services and different dates of services that would be inconsistent with the type of service rendered.

Analysis of Alleged Fraud Proof Points from the Government

1. Although there are over $7 million in fraudulent billings and over $2 million in alleged payments that were obtained fraudulently in the government's data, the Government only provides complete detail on patient records and doctors' orders for seven (7) patients. Based on the information available to me provided by counsel, the data is available for these patients and the respective alleged fraudulent amounts:

Patient	Insurance	Total Suspected Fraud	
		Amt Billed	Amt Paid
Landis	Aetna	$ 3,881.00	$ 2,217.60
Murphy	Aetna	$ 2,060.00	$ 36.00
Barber	Aetna	$ 2,096.00	$ 712.32
Solmor	Aetna	$ 115.00	$ 133.75
Bennett	UHG	$ 3,055.00	$ 1,089.01
Harttrup	UHG	$ 3,615.00	$ 3,315.00
Foster	Cigna	$ 2,460.00	$ 1,476.00
		$ 17,282.00	**$ 8,979.68**

2. Of the approximate 31,761 separate billings produced by the Government, these seven (7) patients are the only ones where an audit trail is provided, and it omits all clinical records. Holter Labs billed services since 2005 for 18,791 patients.[74]

3. This is equivalent to a sample size of (7 patients divided by 31,761 claims or 7/31761) which equals two tenths of one percent of the data (0.02204%). This sample size would not in my opinion be able to extrapolate to fraud for the majority of these claims, and would not meet the test of 'reasonable degree of certainty' to which one would be held as an expert in a civil trial ("…in a civil trial, a party may prevail with as little as 51 percent probability (a preponderance))[75] and certainly not meet the standard "beyond a reasonable doubt" in a criminal trial. [76]

4. It is not clear if the clinician requested additional services beyond the basic cardiac monitoring or that any such studies in the evaluation and treatment of the patient. While there appears to be a single order for 24-hour monitoring, multiple days of service with different claims ids where billed for a variety of services. I do not have the documentation to show whether the multiple 24-hour monitoring events were ordered or not ordered.

These orders occur within the space of 1 to 2 weeks' time. I defer to a physician's judgement as to whether it would be medically necessary to order multiple 24-hour monitoring in one to two weeks' time.

Assessment: A case could be made that the additional services beyond the standard ECG monitoring codes 93226 and 93232 where neither requested nor needed by the ordering clinician. Based on existing information it appears that multiple monitoring services where done on multiple days in a short period of time. This would not seem reasonable and there is no evidence that I can see that these services where ordered.

5. The government states that it appears that the device(s) used did not have the ability to provide remote access to data and nor the ability to provide patient externally activated recordings over 30 days. My understanding is that the device stores data in a static memory system and can be downloaded by the physician and sent to Holter Labs, therefore both the remove capability and the capability to record data for over 30 days are possible.

Assessment: Government's alleged fraud for the following services would be consider cannot be considered inappropriate without more information which has not been provided, specifically

- **a.** the physician's order,
- **b.** the documentation of which device was used,
- **c.** the diagnostic report.

93229	REMOTE 30-DAY ECG TECH SUPP
93271	XTRNL PT ACTIVATED ECG REC DWNLD 30 DAYS

6. The Government states that equipment used does not appear to be able to provide EEG capability required for a standard EEG assessment and patient interviewed reported there were no cranial leads.

Assessment: If this is true, billing for the following service would be considered inappropriate and could be considered fraudulently billed for all claims. However, I have no data proving what device was used. Patients often do not remember what services were performed a few weeks after receiving medical care. It is possible that given there were four years elapsed time between these service dates and the patient interviews that they may have forgotten, particularly if they had chronic (ongoing) symptoms and treatments. Again,

we have a sample size of only seven patients for 31,000 plus in medical claims, which is not a statistically valid sample.

95827 NIGHT EEG

7. The equipment allegedly used allegedly does not appear to support the various respiratory and other component of a sleep study.

Assessment: If this is true, billing for the following service would be consider inappropriate and could be considered fraudulently billed for all claims. However, I have no data proving what device was used.

95806 SLEEP STUDY UNATT&RESP EFFT

8. The equipment available does not appear to support micro T-wave assessment.

Assessment: If this is true, billing for the following service would be consider inappropriate and could be considered fraudulently billed for all claims. However, I have no data proving what device was used.

93025 MICROVOLT T-WAVE ASSESS

1. Cardiac autonomic testing requires a correlation between a physical maneuver observed by the physician and a correlated ECG to determine the result. It allegedly does not appear the current offering can provide this correlation. **Assessment:** If this is true, billing for the following service would be consider inappropriate and could be considered fraudulently billed for all claims. However, I have no data proving what device was used.

95921 AUTONOMIC NERVE FUNCT TEST

Summary of Gaps in the Government's Sampling Methodology

13. The Government used a limited set of seven (7) patients out of over 31,761 claims transactions that produced unreliable extrapolated amounts of alleged fraud.

14. For this limited set of seven (7) patients:

c) There appears to be evidence that services were provided and that no supporting clinical documentation is available as to whether those services were requested by a clinician or not.

d) There is evidence that multiple service encounters for the same type of service were provided in relatively short time frame. This may be a reason to audit Holter Lab's claims, but no audits were performed by any health plan.

e) Typically, such audits are conducted by the payor who received the claim. Based on the documents available to me, there are nineteen (19) health plans that received claims, and then either denied claims or paid claims for services billed by Holter Labs. Each health plan would have the discretion to audit those claims.

f) To confirm that there is truly fraudulent intent requires that the service requested by the clinician and the intent of the clinician in ordering those tests is matched to the service provided by Holter Labs LLC using a statistically valid sample size.

g) To achieve an audit of a statistically valid sample and evaluate whether these claims are valid or fraudulent, one would need to either look at a statistically valid sample across all nineteen payors, or have a very large sample size of claims that had been previously evaluated by at least one payor. Neither of these are available.

15. Once the sample size has been secured, a calculation of the actual fraudulent amount, if any, would require linkage of provider ordering documentation and billing linked to the relevant Holter Lab LLC billing for claims in question as to billing for services not ordered, the report to the physician, and for those claims the government has categorized as "unable to perform" due to alleged use of a device that is incapable of performing a specific procedure, proof of which device was used. The only way to prove which device was used is to contact the physician who used the device, because this data is not present on the health care claim, the order by the physician, or the report that is provided from the device by Holter Labs back to the physician.

16. Proving that services were provided when not ordered will require more complete data for claims and documentation from both the client and Holter Labs LLC. To provide a statistically valid projection of fraud with a 99% confidence level and a margin of error of 5%:

B. The complete data would need to be analyzed by at least 652 of the 31,761 claims, or a sample of 2.05% (z score of 1.96 or nearly two standard deviations from the mean).

$$Sample\ Size = \frac{\frac{z^2 \times p(1-p)}{e^2}}{1+(\frac{z^2 \times p(1-p)}{e^2 N})}$$

Figure 24 - Population size = N, margin of error = e, z score = z.

17. Similarly, to conclude with 95% certainty and a 5% margin of error that specific claims such as the 3,171 claims denoted with CPT code **93025** are fraudulent, at least 343 claims would have to be completely analyzed. A complete analysis would require determining whether the procedure was performed as described "Microvolt T-wave alternans testing is performed to assess patients who are at risk for sudden cardiac arrest due to previous heart attack, heart failure, left ventricular dysfunction, unexplained syncope, or family history of sudden cardiac arrest. A set of 14 electrodes are distributed on the torso and attached to the ECG machine. Seven are standard electrodes while the other seven are special microvolt T-wave alternans sensors. ECG recordings are obtained while the patient walks on a treadmill while slowly increasing treadmill speed to increase the heart rate gradually. Alternatively, heart rate may be increased pharmacologically or using a pacer. The special microvolt T-wave alternans sensors are able to detect extremely small changes in the T-wave portion of the ECG that are not visible to the naked eye on the ECG recording. The test continues until T-wave changes are detected or until the patient achieves the desired heart rate without evidence of T-wave changes. The physician reviews the ECG and provides an interpretation of findings with a written report. including viewing the patient chart, the physician's order, the actual service provided, evidence of what device was used which is not contained in the insurance claim, the insurance claim submitted, the amount paid, and whether the insurance company denied the claim, audited the records or provided a reason for not paying the claim to determine whether it is true that $1,106,777.76 was fraudulently billed and $314,153.63 was fraudulently received.
    - According to the information made available to me, Government data made available to me by counsel, payments were made by the following payors, each of which would have to be verified:
        - Aetna
        - Anthem

- BCBS of Alabama
- BCBS of Florida
- BCBS of Minnesota
- BCBS of New Jersey
- BCBS of Rhode Island
- BCBS of South Carolina
- Cigna
- Emblem Health
- GEHA
- Healthfirst
- Humana
- Independence Blue Cross
- Independent Health
- Premera
- Tricare
- United Health Group
- XL Health

18. Similarly, to conclude with 95% certainty and a 5% margin of error that 4,967 claims denoted with CPT code **93226** are fraudulent, at least 357 claims would have to be completely analyzed. A complete analysis would include confirming whether these steps were completed:

    - Electrocardiographic (ECG) rhythm-derived data is gathered for up to 48 hours of monitoring as the patient goes about regular daily activity while wearing an external ECG recording device, also called a Holter monitor. Electrodes or leads are placed on the patient's chest, and the patient is instructed on the use of the monitor. The recording device makes continuous, original ECG wave recordings for a 12 to 48-hour period. The recordings are captured on magnetic tape or digitized medium to be reviewed later. At the end of the recording period, the patient returns to the office with the device. Stored data derived from the continuous recordings of the electrical activity of the heart include heart rhythm and rate, ST analysis, variability in heart rate and T-wave alternans. Visual superimposition scanning is done to give a 'page review' of the entire recording, identifying different ECG waveforms with selective samples of rhythm strips. A report is made after analysis of the scanning, and the physician or other qualified health care professional reviews and interprets the data for heart arrhythmias. connection, recording, and disconnection.

- Each claim would need to be verified including viewing the patient chart, the physician's order, the actual service provided, evidence of what device was used (and since this is an alleged duplicate claim whether the claim was duplicated for fraud, duplicated as an additional request for payment, duplicated because the date is in close proximity to another date of service for legitimate reasons or fraudulent reasons) which is not contained in the insurance claim, the insurance claim submitted, the amount paid, and whether the insurance company denied the claim, audited the records or provided a reason for not paying the claim to determine whether it is true that $297,808.86 was fraudulently billed and $90,669.54 was fraudulently received.
- According to the information made available to me, Government data made available to me by counsel, payments were made by the following payors, each of which would have to be verified:
  - Aetna
  - Anthem
  - BCBS of Alabama
  - BCBS of Florida
  - BCBS of Minnesota
  - BCBS of New Jersey
  - BCBS of Rhode Island
  - BCBS of South Carolina
  - Cigna
  - Emblem Health
  - GEHA
  - Healthfirst
  - Humana
  - Independence Blue Cross
  - Independent Health
  - Premera
  - Tricare
  - United Health Group
  - XL Health

19. In my opinion, if and only if it is determined using methods above including a statistically valid sample size that it was not possible for Holter Labs to provide the services billed consistent with the standard of practice for these studies, each of those service claims could be considered

fraudulent. In that case, the calculation of the amount of fraudulent billing could be based on billed claims with those service codes.

Exhibit D – Materials Reviewed

A. Provided by Counsel

Section 3

3 Client outline prepared by counsel

3a 1 Crowley debtor exam, March 19 2015, Judgement Debtor Examination
Table of Contents
Client case outline

3a 2 Verified Complaint Cast v. Holter filed October 24, 2012

3a 3 Verified Cross-Complaint Cast v. Holter filed November 18, 2013

3a 4 Default Judgement Request filed April 10, 2014

3a 5 Holter Requsets for Production to Plaintiff James Cast, Set One

3a 6 Cast Response to Requests for Production Set One

3a 7 Declaration in Support of Attorney's Motion to be Relieved as Counsel Civil for Cast and Crowley. Attorney Benjamin Flint III - July 28, 2014

3a 8 Declaration in Support of Attorney's Motion to be Relieved as Counsel – Civil for Cast 2 Attorney Kevin Day – May 12, 2014

3a 9 Declaration in Support of Attorney's Motion to be Relieved as Counsel – Civil for Crowley Attorney Kevin Day - May 12, 2014

3a 10 Minute Order Re Relief of Counsel September 4, 2014

3a 11 Defendants Holter Labs and Michael Mirando's reply in support of their motion to require plaintiff to furnish a security pursuant to Corp. Code 17501

3a 12 Miscellaneous Emails Between Holter Counsel and BK Lawyer

3a 13 Emails Between Jim Cast and Michael Mirando

3a 14 Emails from Jim Cast to Mirando/ Holter Labs

3a 15 Miscellaneous emails between Crowley and Mirando

3a 16 Defense Holter Labs, LLC's requests for admission to Plaintiff James Cast, Set One April 4, 2014

3a 17 Cast's Supplemental Response to Request for Admission Set no. One

3a 18 Deposition of Olena Burns August 11, 2014

3a 19 JP Morgan Chase Account Records for Holter Labs, LLC

3a 20 Cast Medical Services, LLC corporate filings

3a 21 Civil Docket for case USA ex Rel Jamse Case, et al v. National Cardio Labs, LLC, et. al. filed 1-16-04

3a 22 First Superseding Information re USA v. Parsons filed January 24, 2007

3a 23 Miscellaneous emails between Mirando and Counsel

3a 24 Holter Labs Inc Medicare approval for IDTF September 19, 2014

3a 25 Specialized Medical, LLC corporate filing February 27, 2012

3a Defense Discovery Disclosure Table of Contents December 13, 2016

Section 4 Production 1

2. Cast v. Mirando

Cast v. Mirando Holter Labs, LLC's answer to the verified first amended Complaint filed November 18, 2013

Cast v. Mirando, Answer of Stanton Crowley to Verified Cross- Complaint - 1 filed November 25, 2014

Cast v. Mirando Case Summary

Cast v. Mirando Verified Cross-Complaint Filed November 18, 2013

Cast v. Mirando Default Judgement filed August 12, 2014

Cast v. Mirando Verified First amended shareholder derivative complaint filed March 15, 2013

Cast v. Mirando Michael - Mirando's answer to the verified first amended complaint filed November 18, 2013

Cast v. Mirando – Notice of Change of Address filed January 30, 2015

Cast v. Mirando – Register of Actions

Cast v. Mirando – Request for Dismissal filed December 2, 2014

Cast v. Mirando Verified Complaint filed October 24, 2012

Cast v. Mirando FBI electronic communication – obtained some court documents 3/18/15

Cast v. Mirando – Holter Labs, LLC notice of motion and motion to require plaintiffs to furnish a security pursuant to corporate code section 17501

3. Websites

http://holterlabs.com/faq.php FAQ's

http://holterlabs.com/ How to Start

http://holterlabs.com/services.php Services

http://holterlabs.com/ What we do

http://holterlabs.com/ Your benefit

4. Database Queries

Clear searches; NCIC checks September 23, 2013 FBI Electronic Communication

Holter Labs LLC California Secretary of State Business Entity Detail

Holter Labs California CLEAR Business Report

Holter Labs Oregon CLEAR Business Report

Michael Mirando CLEAR National Comprehensive Report

Mirando NCIC

Mirando DMV Image Record

Mirando, Finzer, West Coast

- CLEAR.4 Companies November 4, 2014
- CLEAR Michael Mirando
- CLETS Oregon + DMV
- D&B Global Reference Solution – Report Page: Pelagic
- D&B Global Reference Solution – Report Page: Finzer Properties, LLC
- Business Registry Business Name Search Finzer LLC, Oregon
- ACCURINT Michael J Mirando Properties
- ACCURINT Mirando
- ACCURINT Mirando + OR
- Business Registry Business Name Search Pelagic Properties LLC, Oregon
- FBI Electronic Communications – Results of database searches for Michael Mirando and four identified companies November 7, 2014
- Business Registry Business Name Search West Coast Home Solutions LLC
- Business Registry Business Name Search West Coast Real Estate Holdings LLC
- Spreadsheet ACCURINT Finzer, Pelagic, West Coast Home Solutions, West Coast Real Estate Holdings

Request to run Mirando in TECHs

Holter Labs Amended Annual Report efiled December 1, 2014 Oregon Secretary of State

Holter Labs Articles of Organization efiled November 14, 2012

Holter Labs Articles of Conversion filed March 16, 2013

WHOis.net lookup holterlab.com

5. Holterlabs.com Screenshots

Holterlabs.com.FAQ.2.screen shot.03.30.2016.pdf

Holterlabs.com.FAQ.screen shot.03.30.2016.pdf

Holterlabs.com.Home page.screen shot.03.30.2016.pdf

Holterlabs.com.Home.how to start.screen shot.03.30.2016.pdf

Holterlabs.com.Home.your benefit.screen shot.03.30.2016.pdf

Holterlabs.com.pdf

Holterlabs.com.Request Supplies.Contact Us.screen…ot.03.30.2016.pdf

Holterlabs.com.Services.screen shot.03.30.2016.pdf

FBI Electronic Communication: Screenshots taken on Holterlabs.com

6. Godaddy.com

Contact Info for Shopper ID 5980856 -holterlabinc Domain Information, Audit Histroy

GoDaddy Response to Court Order

GoDaddy Correspondence with FBI

GoDaddy Declaration of Custodian Certifying Business Record

GoDaddy Service of Court Order

Import Form – WHOis search for domain registrar for Holterlabs.com March 29, 2016

WHOis.net lookup holterlabs.com

7. Health Markets

Health Markets correspondence with FBI September 30, 2013

8. Holter Labs Inventory

IntriConDatrix Records

Barbara Streagle, technician, Intricon Datrix, interviewed 4/1/16

Interview with Jon Barron

Address for Caird Technology (Software Company)

Flyer for Datrix VX3

Interview of Jon Barron General Manager of Datrix on 3/19/14

- Lynn Medical Invoices
- Sample Device Label
- Response to Federal Grand Jury Subpoena
  - Intricon Datrix Declaration of Custodian
  - Intricon Datrix Subpoena to Testify April 4, 2016
  - Intricon Datrix Invoice 5/18/2011
  - Intricon Datrix Response to Subpoena April 5, 2016
  - Official Record of Intricon Datrix response to subpoena April 8, 2016
- Response to HIPAA subpoena
  - FBI Import Form: IntriCon Datrix HIPAA subpoena November 15, 2013

- IntriCon Datrix Response to HIPAA subpoena
- IntriCon Datrix Subpoena to appear
- Repair Invoices IntriCon Datrix

Lead-Lok Records

- Lead-Lok Response March 30, 2016
  - Invoice Number 0100882-IN
  - Invoice Number 0101234-IN
  - Invoice Number 0101677-IN
  - Invoice Number 0102195-IN
  - Invoice Number 0102668-IN
  - Invoice Number 0103150-IN
  - Invoice Number 103290-IN
  - Invoice Number 103818-IN
  - Invoice Number 0104323-IN
  - Invoice Number 0104757-IN
  - Invoice Number 0105080-IN
  - Lead-Lok Response to FGJ subpoena April 5, 2016
  - Email response to FBI from Lead-Lok
  - Lead-Lok FGJ subpoena with proof of service March 30, 2016
  - Screen shot of Invoices from Lead-Lok
- Lead-Lok Response September 28, 2015 Email
  - from Lead-Lok to FBI 9-28-15
  - Interview with Chris Healy, VP of Lead-Lok

Customer Contact Information
Customer Credit Card Maintenance AMEX
Holter Labs Transactions with Lead-Lok 12-4-12 to 3-25-14
Invoices 1-25-2005 to 11-29-12
FGJ subpoena with return of service August 18, 2015
Invoice 0095045-IN
Invoice 0095046-IN
Invoice 0095656-IN
Invoice 0095986-IN
Invoice 0096243-IN

Invoice 0096362-IN
Invoice 0096924-IN
Invoice 0097253-IN
Invoice 0097664-IN
Invoice 0098086-IN

Vermed Response

Declaration of Custodian of Records May 13, 2016
Holter Labs Invoices from Vermed
Vermed Respond to FJG subpoena

Lynn Medical Records

Lynn Medical FJG Subpoena March 29, 2016
Lynn Medical Correspondence March 31, 2016
Lynn Medical Invoice February 8, 2010
Lynn Medical Invoice February 18, 2009
Lynn Medical Invoice March 24, 2010

Lynn Medical Invoice April 5, 2006

Lynn Medical Invoice February 8, 2010
Lynn Medical Invoice May 21, 2009
Lynn Medical Invoice June 2, 2010
Lynn Medical Invoice June 14, 2005
Lynn Medical Invoice June 28, 2005
Lynn Medical Invoice July 9, 2007

Lynn Medical Invoice July 22, 2005

Lynn Medical Invoice July 26, 2005

Lynn Medical Invoice July 28, 2005

Lynn Medical Invoice September 24, 2008

Lynn Medical Invoice September 28, 2009

Lynn Medical Invoice November 12, 2010

Lynn Medical Return of Service for subpoena

Lynn Medical Response to FJG subpoena

Lynn Medical's Response to HIPAA subpoena November 27, 2013

Lynn Medical Equipment Transactions Spreadsheet for Holter Labs

Pulse Biomedical Records

PBI Document production 04-04-2016

Pulse Biomedical correspondence to FGJ subpoena

Pulse Biomedical Declaration of Custodian of Records 4-4-2016

Pulse Biomedical FGJ subpoena with POS 3-30-2016

Email Correspondence Mirando and Pulse Biomedical

Pulse Biomedical Response to FGJ subpoena 4-8-2016

9. Interviews

Interview of Jim Cast

Interview of Jon Barron, Attachments

Address for Software Company- Caird Technologies

Flyer DR512 VX3 Model

Lynn Medical Invoices

Sample Device Label

Interview of Andrew Escobar

Interview of Belen Perazzo Barber

Interview of John Harttrup

Interview of Jon Barron

Interview of Lisa Murphy

Interview of Lisa Solmor

Interview of Marla Landis

Interview of Martha Bennett

Interview of Stacy Sixtos Foster

Interview of Stanley Klein

Interview of Ivan Polanco- Practice Manager of Optum Care Medical Group

Interview of Kimberly Smith, Medical Assistant of Dr. Ruby Simpkins

Stanton Crowley

Emails

Interview Notes

Interviews RE SC

Attachment Amended Complaint 9-17-2013

Attachment Blue Cross payment notifications 9-17-2013

Attachment Complaint

Attachment Holter Labs Documents

Attachment Immunity Agreement

Interview of Stanton Crowley 9-17-13

Interview of Stanton Crowley 9-23-13

Attachment Contact Listing 4-11-14

Attachment Inventory List 4-11-14

Attachment Mednet.Heartrak 4-11-14

Attachment Patient List 4-11-14

Interview of Stanton Crowley 4-11-14

Crowley email 5-12-14

Interview of Stanton Crowley 5-14-14

Interview of Stanton Crowley 11-7-14

11. Murrieta Medical Supply

Fictitious Business Name Statement Murrieta Medical Supply 3-27-14

Orange County Clerk Recorder Fictitious Business Name Statement Murrieta Medical Supply

12. Request for Investigative Assistance Enrollment

Aetna response for enrollment documentation

Anthem

Email correspondence from Carl Reinhardt

Import from Carl Reinhardt

NHCAA request letter Blue Cross of CA

Cigna

Request for Enrollment Application

Response to Request

Optum

UHG response to request for enrollment documents

Request for Enrollment Documents

13. Surveillance

Physical Surveillance Finzer 5-6-16 Physical Surveillance Mirando 5-11-16 Physical Surveillance Mirando 5-18-16 Physical Surveillance Mirando 5-23-16

Section 5 Production 2

8. Declaration of Custodians – Various

Ally Bank 9-22-14 Declaration FGJ

Bank of America 9-28-15 Declaration

FGJ Bank of the West 4-2-14

Declaration FGJ Capital One 3-17-15

Declaration FGJ Capital One 10-20-15

Declaration FGJ

Fidelity National of Oregon 9-24-14 Declaration

FGJ JP Morgan Chase 10-14-14 Declaration FGJ

Lea Lacsoon 6-4-15 Declaration

Wells Fargo Bank 10-6-15 Declaration

15. Miscellaneous Documents

Bank of America account RE Murrieta Medical Deposits

16. Bank Schedules

Ally Bank Mirando Account 5-19-10 to 3-15-16

Bank of America Murrieta Medical Supply 2007-2012 Bank of the West Holter Labs LLC 2010-

2012

Chase

Holter Labs 2005 – 2013

Mirando 2008 - 2014

ING Mirando 2005-

2016 US Bank Holter

Labs

US Bank - Mirando dba Holter Labs 2012-

2013 US Bank - Holter Labs 2013- 2016

19. Financial Records

Ally Bank

Ally Bank Production 4-12-16

FGJ subpoena requests document production 4-12-16 Ally Bank response to subpoena 4-8

-16

Ally Bank monthly statements September 2015 to March 2016

SD card containing aircraft video surveillance in

Portland Surveillance request for Michael Mirando 5-

6-16

Ally Bank Customer Service Screen

Ally Bank Declaration of Custodian

Ally Bank FGJ subpoena with proof of serve 3-24-16

Ally Bank Screen shot of Mirando account 4-5-16

Bank of America

Bank of America production 9-22-15

Bank of America signature cards

Bank of America response to FJG subpoena 9-22-15

Bank of America FGJ subpoena with proof of service 8-19-15

Bank of America correspondence- password for CD

Bank of America Custodian of Records Affidavit 9-21-15

Bank of America Checking Account Statement Mirando 2007-2012

Bank of the West

Bank of the West description of response to FJG subpoena 4-2-14

Bank of the West Declaration of Custodian 3-12-14

Bank of the West account records for Holter Labs LLC

Bank of the West checks

Bank of the West deposits from 2010 to 2012

Bank of the West FJG subpoena with proof of service 3-13-14

Bank of the West banks statements from 4-2010 to 12-2012

Bank of the West FGJ subpoena 3-6-14

Capital One ING

Capital One FGL subpoena requests 10-10-15

Capital One Production 3/6/2015

Deposited Checks Account 6279769

Deposited Checks Account 133192018

Capital One response to FGJ subpoena 3-17-2015

Capital One ING Custodian of Records

Bank Statements ING and Capital One 3-05 to 1-15

Capital One FJG subpoena 2-9-15

Capital One Production 4-27-16

Capital One correspondence response to subpoena 4-26-16

Capital One debits

Capital One deposited items

Capital One statements 10-15 to 3-16

Capital One wire 3-4-16

Capital One Declaration of Custodian

Capital One FJG subpoena with proof of service 3-24-16

Capital One response to FGJ 4-29-16

Capital One FGJ subpoena, proof of service 4-29-16 Import form

Second FGJ subpoena August 2015

Capital One 360 FGJ subpoena with proof of service 8-18-15

Email correspondence 1-6-16

Kennedy wires

Mirando and Capital One ING correspondence

Capital One ING Declaration of Custodian

ING Statement for Mirando account 5-08

ING Statement for Mirando account 2-15 to 9-15

Chicago Title Company of Oregon

Declaration of Custodian

FJG subpoena with proof of service 8-18-15

Response to FJG subpoena

Escrow documents

Etrade

Documents provided by E Trade Clearing LLC

FGJ subpoena with proof of service 8-25-14

ETrade Activity

Declaration of Custodian

Mirando, Michael – GJ

Account 65845349

Account Profile

Statement 1-30-09

Statement 3-31-09

Statement 6-30-09

Statement 9-30-09

Statement 12-31-09

- Statement 3-31-10
- Online Account Application

Account 66189461

- 2007 Consolidated Form 1099
- 2007 Year End Summary
- 2008 1009 Consolidated amended 1099
- 2008 1009 Consolidated Form 1099
- 2008 Year End Summary correspondence
- 2008 Year End Summary
- 2009 Form 1099 and details
- 2010 Form 1099 and details
- 2011 Form 1099 and details
- 2012 Form 1099 and details
- 2013 Form 1099 and details
- Account profile
- ACH 2007- 2011
- Checks
- Bank Statements 9-07 to 9-14
- OLA Reprint

Account 66799604

- Statements 9-07 to 3-13
- Account Profile
- OLA Reprint

Fidelity National Title Company

- Copies of 6 Checks
- Escrow File
- Title File
- Declaration of Custodian
- FGJ subpoena with proof of service 8-25-14
- Response to FGJ
- Source of funds

JP Morgan Chase

- Declaration of Custodian

- FGJ subpoena and FD 302s
- Chase – Holter Labs LLC
  - Deposits 2005-2010
  - Statements 2005-2013
  - Deposits 2011-2013
  - Signature Card
  - Holter Labs checks signed by Crowly
  - Holter Chase review of account
  - Mirando Checking Account
    - Statements 2008- 2014
    - Signature Card
    - Wires 2009
  - Pelagic Accounts and Bradford Tyler Holdings
    - Bradford Tyler Holdings
      - Statements 2009-2010
      - Signature Card
    - Pelagic Properties of Mississippi
      - Chase Statements 2009-2011
      - Signature Card
    - Pelagic Properties of North Carolina
      - Chase Statements 2006-2014
      - Signature Card
    - Pelagic Properties of South Carolina
      - Chase Statements 2005-2011
      - Signature Card
- Metavante
- Northern Trust Investment
- Northwestern Life
- Ocwen Indymac
- PNC Bank
- US Bank
- Vanguard Group

Vehicles

Audi Wilsonville

Documents produced under FGJ subpoena

Declaration of Custodian

Records of Purchase

Ron Tonkin Toyota

Documents produced under FGJ subpoena

Declaration of Custodian

Records of Purchase

US Bank Leasing

Response to FGJ subpoena 2008 Chevy Corvette

Records 2008 Chevy Corvette

Declaration of Custodian

Vision Financial Markets

Wells Fargo

Home Mortgage Produced 10-15-15

21. Miscellaneous Spreadsheets

Mirando Assets and Summary of Bank Accounts

USA_ 025472 Holter Labs GJ Serials

USA_ 025473 Holter Labs Main file Serial Numbers

24. Miscellaneous Documents

Arrest of Michael Mirando 10/07/16

Attempt to Interview James Brown 10/28/16

James Brown DMV Record

Deliverables

MAC Request form EDI Request for Pametto GBA

MAC Request for EFT Request for Holter Labs

Provider Call Logs SC Part B Palmetto GBA- Medicare B SC

Provider Enrollment Holter Labs IDTF Site Investigation

Email Crowley- Holter Labs partners 9-3-16

RFI Holter Labs Inc 10-13-16

25. Documents

Email Update Kathleen Kennedy to Christopher Kendall: Holter Labs – FD 302s

Indictment Summary of
Evidence Items for AUSA 3-
16-16
Link Chart Chase Bank Account held by Holter Labs

Section 6 Production 3

AdvanceMed correspondence 11-21-16
Holter Labs 12-20-16
AdvanceMed Medicare
Correspondence 11-
21-16 Deliverables
E
D
I
E
F
T
Provider Call Logs
Provider Enrollment correspondence
Provider Enrollment Holter Labs Inc 1-
1-14
Physical Surveillance 9-20-16, 9-28-16, 10-
6-16 Password Medicare Re: Holter Labs 11-21-16
Physical Surveillance 9-20-16
Physical Surveillance 9-28-16
Physical Surveillance 10-
6-16 RFI Holter Labs 10-
13-16

18 Claims Data and Patient Documentation

RIA requests
Anthem request letter 3-29-
16 Holter Labs Request

2005-2008 Holter Labs

Request 2009-2012 Holter

Labs RIA 8-3-15

Holter Labs RIA 9-19-13

Optum request letter 3-

29-16

Premera Blue Cross request letter 3-

29-16 RIA 247 and RIA 249 3-29-16

Holter Lab Reports Samples

Holter Labs Report Hattrup, John 4-11-11 Records

Holter Labs Report partial Landis, Maria 4-27-09

Records Holter Labs Report Solomor 5-28-13 Records

Holter Labs Report Bennett, Martha 12-3-12

Records Holter Labs Report Foster, Stacey 8-10-

11 Records Holter Labs Report Perazzi, Belen 1-

12-10 Records Review of Holter Labs Report

Medicare claims January 2014 to April

2016 Aetna Claims

Anthem Claims

BCBS Alabama

Claims BCBS

Arkansas Claims

BCBS Florida/ Florida Blue

Claims BCBS Hawaii Claims

BCBS Minnesota Claims

BCBS New Jersey

Claims BCBS South

Carolina Claims BCBS

Rhode Island Claims

Cigna Claims

Claims Data from

FBI Coventry

Claims

Data Analysis

Emblem Health Claims

Fraud Analysis by

Government GEHA

Claims

Healthfirst

Claims

Highmark

Claims

Humana

Claims

IHC Health Solutions

Claims Independent Blue

Cross Claims Independent

Health Claims Kaiser

Permanente Claims

Medicare Claims

Patient Files: Insured Beneficiary Interviews

4. Belen Perazzo 1-12-10, 1-13-10, 1-16-10, 1-19-10, 1-23-10

5. Martha Bennett

HCFA 1500

UHG Checks – Paid Bennett

claims UHG claims for Bennett

9. John Hattrup

HCFA 1500

UHG Checks paid Hattrup

billings UHG claims for

Hattrup

10. Interviews with

Beneficiaries Interview

of John Hattrup

Interview of Lisa

Solmor Interview of

Matha Bennett

Interview of Stacey Sixtos (nee Foster)

12. Lisa Solmor

HCFA 1500 5-29-13

Holter Labs Final Appeal for Claim 5-

30-13 Aetna Response to first Appeal 5-

30-13

Non-payment of Claim Notice from Aetna 5-30-13

Aetna Final level of appeal response- Notice of Exhaustion of Appeal 5-

30-13 Second Appeal Holter Labs 5-30-13

Third Appeal Holter Labs 5-30-13

13. Marla Landis

HCFA 1500 4-27-09

HCFA 1500 4-28-09

HCFA 1500 5-8-09

HCFA 1500 5-15-09

HCFA 1500 5-22-09

17. Beneficiaries

Health Insurance Claim

Information Aetna

Correspondence Information

Patient Meza

Patient Solmor

HCFA 1500 Claim Information

Aetna response to RFI

RFI requesting HCFA for claims

Cigna

Request to HCFA 1500

Response to request

H FA forms

C Stacey Foster 1500 HCFA

Optum UHG

Hattrup1500 HCFA Bennett

1500 HCFA Checks to Holter

Labs LLC RFI to UHG

Response to RFI

Patient Insurance Claims data

Aetna Beneficiaries Claims

Cigna Beneficiaries Claims

United Health Group Beneficiaries Claims

Physicians

Donah Bulasan MD

Declaration of Custodian

Response to HIPAA subpoena

HIPAA subpoena with proof of service

Medical Records Meza Murphy Service of

HIPAA subpoena

Gregory Joy MD

Declaration of Custodian

HIPAA subpoena Medical

Records Hattrup

Service of HIPAA subpoena 3-17-15

Jeffery Globus MD

Declaration of Custodian

HIPAA subpoena

Response to HIPAA subpoena

Medical Records Foster

Service of HIPAA subpoena 3-16-15

Richard Richmond MD

Declaration of Custodian

HIPAA subpoena

Medical Records Landis

Medical Records Barber

Medical Records Solmor

Service of HIPAA subpoena

Premera Blue Cross Claims

Provider Enrollment- Palmetto GBA Part B

Tricare Claims

United Health Group Claims

WellCare Health Claims

XL Health Claims

Datrix EEG v ECG

Interview with Jon Barron, General Manager of Intricon Datrix 3-24-14

Indictment

Indictment filed April 5, 2016

Summary of Evidence- Mirando Case, Arrigo annotations

Summary of Evi

B. Citations and Documents Independently Reviewed

Citations and documents independently accessed appear as end notes in this document.

Exhibit E – Prior Testimony

See separate document

Exhibit F – PowerPoint Illustrations

See separate document

1

[1] U.S. Court of Appeals, 9th Circuit, Opinion February 11, 2014 http://cdn.ca9.uscourts.gov/datastore/opinions/2014/02/11/12-10045.pdf

[2] Pay to charge ratio is payment for a healthcare claim divided by the charge for the health care claim. At times the numerator and denominator are reversed (charge divided by payment) and the ratio is then called charge to reimbursement ratio (*see* http://healthaffairs.org/blog/2013/07/15/what-types-of-hospitals-have-high-charge-to-reimbursement-ratios/).

[3] July 14, 2013. Mulestein, Health Affairs Blog. http://healthaffairs.org/blog/2013/07/15/what-types-of-hospitals-have-high-charge-to-reimbursement-ratios/

[4] Collected by: U.S. Department of Health and Human Services
Archived since: Sep, 2013 HHS news and announcements from 1991+. https://archive-it.org/collections/3926?fc=meta_Date:2013 accessed October 5, 2017.

[5] July 14, 2013. Mulestein, Health Affairs Blog. http://healthaffairs.org/blog/2013/07/15/what-types-of-hospitals-have-high-charge-to-reimbursement-ratios/

[6] Collected by: U.S. Department of Health and Human Services
Archived since: Sep, 2013 HHS news and announcements from 1991+. https://archive-it.org/collections/3926?fc=meta_Date:2013 accessed October 5, 2017.

[7] July 14, 2013. Mulestein, Health Affairs Blog. http://healthaffairs.org/blog/2013/07/15/what-types-of-hospitals-have-high-charge-to-reimbursement-ratios/

[8] Collected by: U.S. Department of Health and Human Services
Archived since: Sep, 2013 HHS news and announcements from 1991+. https://archive-it.org/collections/3926?fc=meta_Date:2013 accessed October 5, 2017.

[9] July 14, 2013. Mulestein, Health Affairs Blog. http://healthaffairs.org/blog/2013/07/15/what-types-of-hospitals-have-high-charge-to-reimbursement-ratios/

[10] San Francisco Spine Surgeons, LLC v. Claim Works LLC., JAMS Reference No. 1110018697, hearing held October 2017 in San Jose, California (Ambler, Arb).

[11] It was stipulated in these proceedings by both parties and Judge Ambler that my qualifications deemed me to be an expert on medical coding, billing, insurance reimbursement, and damages / loss calculations.

[12] Kaiser Health News' Phil Galewitz September 2011. Denial rates for insurance policies purchased in the individual market—published for the first time as a result of the provisions in the Affordable Care Act— finds that insurers deny coverage at different rates depending on geographical location and for almost any reason. For instance, a review of the 20 most populous states find that "denial rates routinely exceed 20 percent and often are much higher" and seem to contradict industry claims to the contrary.

[13] Dichara, Jaqueline. Quantify Denial Rates for Smooth Revenue Cycle Management. RevCycle Intelligence. https://revcycleintelligence.com/news/quantify-denial-rates-for-smooth-revenue-cycle-management

[14] August 26, 2016. Lachney, Cameron. Medical Billing Denials Are Avoidable: How to Help Prevent the Top 5 http://www.mckesson.com/bps/blog/medical-billing-denials-are-avoidable/

[15] Gibson, Harold. M-Scribe Medical Billing, August 28, 2014.

[16] Easterling, Sharon. RAC Forensics 101 Part 3: Denials Management, AHIMA. http://bok.ahima.org/doc?oid=103685#.Wdm7FxNSzCI

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[17] Easterling, Sharon. RAC Forensics 101 Part 3: Denials Management, AHIMA. http://bok.ahima.org/doc?oid=103685#.Wdm7FxNSzCI

[18] Health iPass - Reducing the Expenses of Claim Denial Management Through Automation," May 31, 2016. http://insights.healthipass.com/blog/reducing-the-expenses-of-claim-denial-management-through-automation

[19] Gibson, Harold. M-Scribe Medical Billing. August 28, 2014. https://www.m-scribe.com/blog/bid/353875/Top-5-Medical-Claim-Denials-in-Medical-Billing

[20] Gibson, Harold. M-Scribe Medical Billing. August 28, 2014. https://www.m-scribe.com/blog/bid/353875/Top-5-Medical-Claim-Denials-in-Medical-Billing

[21] Woodstock, Elizabeth. Denial Management: Field Tested techniques that get claims paid. Optum.

[22] Gibson, Harold. M-Scribe Medical Billing. August 28, 2014. https://www.m-scribe.com/blog/bid/353875/Top-5-Medical-Claim-Denials-in-Medical-Billing

[23] Gibson, Harold. M-Scribe Medical Billing. August 28, 2014. https://www.m-scribe.com/blog/bid/353875/Top-5-Medical-Claim-Denials-in-Medical-Billing

[24] According to the Mayo Clinic, Neurology department, "Autonomic nerve disorders (dysautonomia) refer to disorders of autonomic nervous system (ANS) function. Dysautonomia is a general term used to describe a breakdown or abnormal function of the ANS. The autonomic nervous system controls much of your involuntary functions. Symptoms are wide-ranging and can include problems with the regulation of heart rate, blood pressure, body temperature, perspiration, and bowel and bladder functions. Other symptoms include fatigue, lightheadedness, feeling faint or passing out (syncope), weakness, and cognitive impairment."

[25] Section 13 - Software Validation & Verification

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http://cairdtech.com/Jim/FDA%20Information/HRV%20FDA%20510K/FDA%20ANS%20510K%205%20-%20pdf/FDA%20markup%20Software%20Validation%20&%20Verification.pdf

[26] Summary of evidence, companion to indictment, page 19, Bates USA_025517 – provided by counsel

[27] Federal Healthcare Fraud Sentencing After Obamacare: Analyzing Title 18 USC 1347 https://www.newyorkcriminallawyer-blog.com/2014/06/federal-healthcare-fraud-sentencing-obamacare.html

[28] Federal Healthcare Fraud Sentencing After Obamacare: Analyzing Title 18 USC 1347 https://www.newyorkcriminallawyer-blog.com/2014/06/federal-healthcare-fraud-sentencing-obamacare.html

[29] U.S. Court of Appeals, 9th Circuit, Opinion February 11, 2014 http://cdn.ca9.uscourts.gov/datastore/opinions/2014/02/11/12-10045.pdf

[30] July 14, 2013. Mulestein, Health Affairs Blog. http://healthaffairs.org/blog/2013/07/15/what-types-of-hospitals-have-high-charge-to-reimbursement-ratios/

[31] Collected by: U.S. Department of Health and Human Services
Archived since: Sep, 2013 HHS news and announcements from 1991+. https://archive-it.org/collections/3926?fc=meta_Date:2013 accessed October 5, 2017.

[32] U.S. Court of Appeals, 9th Circuit, Opinion February 11, 2014 http://cdn.ca9.uscourts.gov/datastore/opinions/2014/02/11/12-10045.pdf

[33] July 14, 2013. Mulestein, Health Affairs Blog. http://healthaffairs.org/blog/2013/07/15/what-types-of-hospitals-have-high-charge-to-reimbursement-ratios/

[34] Collected by: U.S. Department of Health and Human Services
Archived since: Sep, 2013 HHS news and announcements from 1991+. https://archive-it.org/collections/3926?fc=meta_Date:2013 accessed October 5, 2017.

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[35] U.S. Court of Appeals, 9th Circuit, Opinion February 11, 2014
http://cdn.ca9.uscourts.gov/datastore/opinions/2014/02/11/12-10045.pdf

[36] Based on email from Michael Mirando to attorney Ed Robinson forwarded to me dated September 22, 2017 stating 18,791 patients and approximately 34,000 claims.

[37] San Francisco Spine Surgeons, LLC v. Claim Works LLC., JAMS Reference No. 1110018697, hearing held October 2017 in San Jose, California (Ambler, Arb).

[38] Id.

[39] A lay person can easily confirm these calculations using any number of online calculators (provided that the confidence level is above 80% to 99%; for lower standards providing less quality or certainty, other calculators can be used which are referenced in this report in subsequent citations). One easy to use calculator is the Survey Monkey Sample size calculator which can be found at https://www.surveymonkey.com/mp/sample-size-calculator/

[40] My basis for this data and calculation methods are my knowledge training education and experience. Specifically, these topics were covered in my education in statistical analysis at the University of California, Irvine as part of my economics curriculum and in my course at Stanford Medical School, with a focus on Biomedical Informatics in a course focused on Statistical Analysis for Medicine taught by Kristin L. Sainani, PhD an Associate Professor with Health Research and Policy at Stanford University. Sainani's courses are Statistics in Medicine, Writing in the Sciences, Probability and Statistics, Discrete Data Analysis, and Longitudinal Data Analysis. Sainani's work is independently quoted by industry peers in a presentation entitled "Basics of Statistics - Research Statistics" prepared by Jobayer Hossain, PhD and Larry Holmes, Jr. PhD, D.Ph., CPH in October 2008. Hossain and Holmes are employed at Nemours Biomedical Research. Hossain is Manager, Biostatistics Core Research Scientist, Department of Biomedical Research, Nemours Adjunct Associate Professor, Department of Applied Economics and Statistics, University of Delaware.

[41] For example, Raosoft provides a calculator that allows a low standard of confidence level such as 51%. Many online calculators will not even allow such a low level of confidence, since it is a statistically low standard and instead only provide the option to use confidence levels of 80% to 95% to 99%. However if a layperson or other expert wishes to validate my calculations without manually performing the z-score calculations they can be checked here: http://www.raosoft.com/samplesize.html

[42] For each claim and associated medical record, the result of the review / audit will either fraudulent or not fraudulent. Therefore the 'answer' to this question is skewed one way or the other (yes, or no).

[43] NHelp National Health Law Program http://www.healthlaw.org/about/staff/mara-youdelman/all-publications/qa-defining-medical-necessity#.WL4vwhiZP5c June 24, 2004

[44] CMS Coverage Policy - Title XVIII of the Social Security Act, Section 1862(a)(1)(A) states that no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury.

Title XVIII of the Social Security Act, Section 1862(a)(7). This section excludes routine physical examinations.

Title XVIII of the Social Security Act, Section 1833(e) states that no payment shall be made to any provider for any claim that lacks the necessary information to process the claim.

CMS Manual System, Pub 100-02, *Medicare Benefit Policy Manual*, Chapter 15, Sections 60 and 80

CMS Manual System, Pub. 100-03, *Medicare National Coverage Determinations Manual*, Chapter 1, Section 240.4

CMS Manual System, Pub 100-04, *Medicare Claims Processing Manual*, Chapter 1, Sections 10 and 30.2 and Chapter 35

CMS Manual System, Pub. 100-08, *Medicare Program Integrity Manual*, Chapter 3, Section 3.4.1.2, Chapter 10, Chapter 13, Section 13.5.142

Code of Federal Regulations, 410.32 and 410.33

[45] In a case involving a transgender patient "On May 11, 1979, the District Court declared that the **policy of denying Medicaid benefits** for sex reassignment surgery **where it is a medical necessity for treatment of transsexualism is contrary to the provisions of Title XIX of the Social Security Act**, 42 U.S.C. § 1396 (1976), and therefore violates the supremacy clause of the United States Constitution. It declared the relevant parts of the Iowa State Plan void, and permanently enjoined the administration and enforcement of the Iowa Medicaid program in a manner to deny benefits for medically necessary care and treatment incident to sex reassignment surgery or subsequent corrective surgery."[45] The 8th Circuit Court of Appeals affirmed the decision of the lower court.

In *Pinneke v. Preisser,* 623 F.2d 546, 550 (8th Cir. 1980) (recognizing that "the decision of whether or not certain treatment or a particular type of treatment is 'medically necessary' rests with the individual recipient's physician and not with clerical personnel or government officials");

[46] Title XVIII of the Social Security Act section 1862 (a)(1)(A). This section allows coverage and payment of those services that are considered to be medically reasonable and necessary.

Title XVIII of the Social Security Act section 1862 (a)(7). This section excludes routine physical examinations and services.

[47] Title XVIII of the Social Security Act section 1862 (a)(1)(A). This section allows coverage and payment of those services that are considered to be medically reasonable and necessary.

Title XVIII of the Social Security Act section 1862 (a)(7). This section excludes routine physical examinations and services.

[48] Medicare LCD - Local Coverage Determination Independent Diagnostic Testing Facility (IDTF) (L35448)

[49] http://www.medicarepaymentandreimbursement.com/2011/10/special-electroencephalography-eeg-cpt.html

[50] https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/downloads/independentdiagnostictestingfacility.pdf

[51] U.S. Court of Appeals, 9th Circuit, Opinion February 11, 2014 http://cdn.ca9.uscourts.gov/datastore/opinions/2014/02/11/12-10045.pdf

[52] Medicare Cost Reports. CMS.gov, https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Cost-Reports/

[53] These requirements govern whether an entity or individual is qualified to provide services to Medicare patients rather than whether particular items or services provided by a provider are covered by and properly billable for payment from the Medicare program. These provisions are referred to by three essentially interchangeable terms. *See* 42 C.F.R. Subpart G, Parts 482-498.

- "Conditions of participation" for hospital, skilled nursing facility and home health agencies; 42 C.F.R. Parts 482, 483 (Subpart B) and 484.
- "Conditions for coverage" for suppliers, including individual physicians and practitioners; *See, e.g.*, 42 C.F.R. Part 498
- "Conditions for certification" for rural health clinics, 42 C.F.R. Part 491 (Subpart A), and clinical laboratories. *See* 42 C.F.R. Part 493 (CLIA certification requirements).
- A lapse in compliance with a COP should not, and to date has not been held to, affect the propriety of billing, so
- long as the provider retains its provider agreement (colloquially, "remains a currently-certified Medicare provider")
- and billing privileges. Medicare Program Integrity Manual, CMS Pub. 100-08 (hereafter "PIM"), Chap. 3, § 3.1A
- (emphasis added). Some COPs, however, are also considered conditions of payment based on particular regulatory
- language or the provisions of provider agreements or provider certifications.

[54] Conditions of Payment are statutory and regulatory provisions that specify that Medicare payment shall not be made unless the condition is satisfied, such as specific exclusions from coverage, 42 U.S.C. § 1395y, documentation requirements, 42 U.S.C. § 1395*l*(e), and the Stark self-referral prohibition. 42 U.S.C. § 1395nn. Certain other statutory and regulatory requirements, including some provisions, which, by their own terms, appear to be COPs may become Conditions of Payment based on required provider certifications or terms of provider agreements. *See, e.g.*, 42 U.S.C. § 1320a-7b(b), the anti-kickback statute. *See also U.S. ex rel. Hutcheson v. Blackstone Medical, Inc.*, 647 F.3d 377 (1st Cir. 2011); *cf. U.S. ex rel. Mikes v. Straus*, 247 F.3d 687 (1st Cir. 2011).

[55] Medicare statutes are referenced here because the Centers for Medicare and Medicaid tend to set standards for themselves as the Federal payor, which are then adopted by other payors and for

medical billing statements for cash pay. Since states have phased in of Medicare standards for Workers Compensation billing they are applicable to this report and my opinion.

[56] 42 U.S.C. § 1395y(a)(1); 42 C.F.R. § 411.15(k)(1).

[57] 42 U.S.C. § 1395*l*(e) ("No payment shall be made . . . unless there has been furnished such information as may be necessary in order to determine the amounts due . . . for the period with respect to which the amounts are being paid or for any prior period").

[58] See Case of *The Inspector General V. Respondent [George Kern MD], HHS Departmental Appeals Board, Docket No. C-25 (CR12) (August 26, 1987) (emphasis added).*

[59] 42 U.S.C. § 1320a-7(b)(11).

[60] 42 U.S.C. § 1320c-3(a)(1).

[61] 42 CFR §410.32 states that all diagnostic tests must be ordered by a physician who is treating the beneficiary, and test results must be used in the management of the beneficiary's specific medical problem

[62] Joseph Nichols MD Health Data Consulting in presentations to the Workgroup for Electronic Data Interchange (WEDI), an industry standards group that advises Federal Standards groups such as the HHS Office of the National Coordinator on electronic data standards in healthcare. Dr. Nichols reviewed the claims of all 50 state Medicaid as well as Guam and Puerto Rico during the transition to ICD-10 from 2013 to 2015.

[63] AAPC (American Academy of Professional Coders) is an accepted standards education and certification organization for medical coder certification, especially for outpatient coding.

[64] State Medicaid and CHIP Income Eligibility Standards1 Expressed in Monthly Income, Household Size of One (For MAGI Groups, based on state decisions as of October 1, 2014) https://www.medicaid.gov/medicaid-chip-program-information/program-information/downloads/medicaid-and-chip-eligibility-levels-table_hhsize1.pdf accessed May 31, 2016

[65] Comparing CPT Code Payments for Medi-Cal and other Payers. Price Waterhouse Coopers, accessed May 31, 2016 http://www.chcf.org/~/media/MEDIA%20LIBRARY%20Files/PDF/PDF%20C/PDF%20ComparingCPTCodePayments.pdf

[66] Centers for Medicare and Medicaid, ICN 006819 December 2015 https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/AmbSurgCtrFeepymtfctsht508-09TextOnly.pdf

[67] Source: CMS, Hospital Outpatient Prospective Payment System, Partial Hospitalization services furnished by hospitals or Community Mental Health Centers, Ambulatory Payment System https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/HospitalOutpaysysfctsht.pdf

[68] Source: CMS, coverage of imaging services. https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/Radiology_FactSheet_ICN907164.pdf

[69] Medicare Claims Processing Manual Chapter 23 -Fee Schedule Administration and Coding Requirements

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c23.pdf

[70] American Medical Association http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/cpt/about-cpt.page?

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71 Source: http://www.ncvhs.hhs.gov/meeting-calendar/agenda-of-the-december-9-10-2003-ncvhs-subcommittee-on-standards-and-security-hearing/consolidated-health-informatics-initiative-final-recommendation-information-sheet-billingfinancial-for-the-december-9-2003-ncvhs-subcommittee-on-standards-and-security-hearing/

72 Source: American Medical Association CPT Code Book

73 Excludes Medicare

74 Based on email from Michael Mirando to attorney Ed Robinson forwarded to me dated September 22, 2017 stating 18,791 patients and approximately 34,000 claims.

75 This citation is being provided to speak to statistical probability and error rates in expert opinions, not as my legal interpretations or legal conclusions. Beyond a Reasonable Doubt, US Legal "Beyond a Reasonable Doubt [is the] standard of proof is used exclusively in criminal cases, and a person cannot be convicted of a crime unless a judge or jury is convinced of the defendant's guilt beyond a reasonable doubt. Precisely, if there is any reasonable uncertainty of guilt, based on the evidence presented, a defendant cannot be convicted. Ostensibly, this burden requires that a trier of fact (judge, jury, arbiter) is fully satisfied and entirely convinced to a moral certainty that the evidence presented proves the guilt of the defendant. There is essentially no room for wavering or uncertainty; the trier of fact believes the evidence to be precise, indubitable, and leaves one with an inescapable conclusion of certainty. Whereas, in a civil trial, a party may prevail with as little as 51 percent probability (a preponderance), those legal authorities who venture to assign a numerical value to "beyond a reasonable doubt" place it in the certainty range of 98 or 99 percent. In a criminal trial, the state must prove that the defendant is guilty, and the burden of proof is always with the state for the **case in chief.** The defendant, carrying a presumption of innocence, has no burden of proof, and need prove nothing. A defendant may sit mute at a criminal trial, because the state has the burden of proof to show that the defendant satisfied each element of the statutory definition of a crime by his or her action/participation or failure to act. Any evidence offered by the defense is generally directed

toward discrediting or undermining the state's evidence, and does not contribute to any evidentiary burden. https://courts.uslegal.com/burden-of-proof/beyond-a-reasonable-doubt/

[76] This citation is being provided to speak to statistical probability and error rates in expert opinions, not as my legal interpretations or legal conclusions. Jack B. Weinstein and Ian Dewsbury Law Probability and Risk Oxford Academic. For example, in theory, the 'presumption of innocence' should mean that, before hearing any evidence, the jury should start with the assumption that it is close to 0% likely that the defendant (out of all the people in the universe) committed the crime charged. In practice, most trier's initial anchoring assumption is probably considerably higher than this. Jurors will assume, to some extent, depending on their individual beliefs about how the criminal justice system works (and despite directions not to do so), that if there were no substantial evidence of guilt: (a) the prosecutors and investigators would not have gone forward with the case, (b) the grand jury would not have indicted and (c) the trial judge would not have started up the machinery of selecting a jury and holding a trial. Some jurors also probably have been swayed towards or away from a preliminary hypothesis of guilt or innocence by the jury selection process and opening statements of counsel. It is not unlikely that many jurors begin hearing evidence believing that it is roughly 50% probable that the defendant committed the offense charged, with the state having the responsibility to drive up this probability. https://academic.oup.com/lpr/article/5/2/167/927735/Comment-on-the-meaning-of-proof-beyond-a

Exhibit E – PowerPoint Illustrations (separate document)

Exhibit F – Prior Testimony as Provided in Federal Rule 26 (separate document)

EXHIBIT B

EXHIBIT F – Supplemental Illustrations
US. v. Mirando
Rebuttal Expert Report Regarding Loss

Prepared by Michael F. Arrigo
marrigo@noworldborders.com
949-335-5580

DATE PREPARED:

OCTOBER 9, 2017

Note: this document is considered an integral part of the Rebuttal Expert Report Regarding Loss, a 132 page document published for filing with the court on October 9, 2017. This Exhibit F by itself does not represent the full measure of Opinions or methods used. I specifically reserve the right to amend my opinions if new facts or new testimony from other experts become available to me.

Topics

- No definitive proof that Device cannot perform medical diagnostic procedures
- FDA data conflicts with Government's report
- Of the fourteen (14) steps involved in determining the veracity of medical claims and billing, coding data, the Government only sheds partial light onto four (4) of those steps.
- Other industry data tends to differ with definitions of 'duplicate'
- Industry standards and statutes mandate that documentation must be reviewed to determine veracity or fraudulent claims

Government States “Impossible” to perform EEG test using Datrix 512 Due to Frequency

- Government based opinion on interview with one individual
- ONE witness, one page document out of 40,000 to 60,000 pages of material states ‘impossible’ to perform test based on frequency
- Witness testimony does not coincide with FDA filing data

What is an FDA form 510(k)?

- A **510**(**K**) is a premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device (21 CFR §807.92(a)(3)) that is not subject to premarket approval.
- Must, among other things state the frequency and bandwidth of the device

Datrix 512 Uses Same Frequency as FDA Approved Device for EEGs

- Findings: Datrix 512 uses same frequency for ECG as other devices that do EEG

K030179

OCT 1 5 2003

datrix

510(K) PREMARKET NOTIFICATION SUMMARY

Company: Datrix
Address: 340 State Place
Escondido, CA 92029
Phone: (760) 480-8874
Fax: (760) 480-9474
Contact Person: Lauren Luhmann

Date Prepared: April 2, 2003

Trade Name: VX3 Series Digital Holter Recorder
Common Name: Ambulatory ECG Recorder
Classification Name: Electrocardiograph, Ambulatory (Without Analysis) (CFR 870.2800)

Description

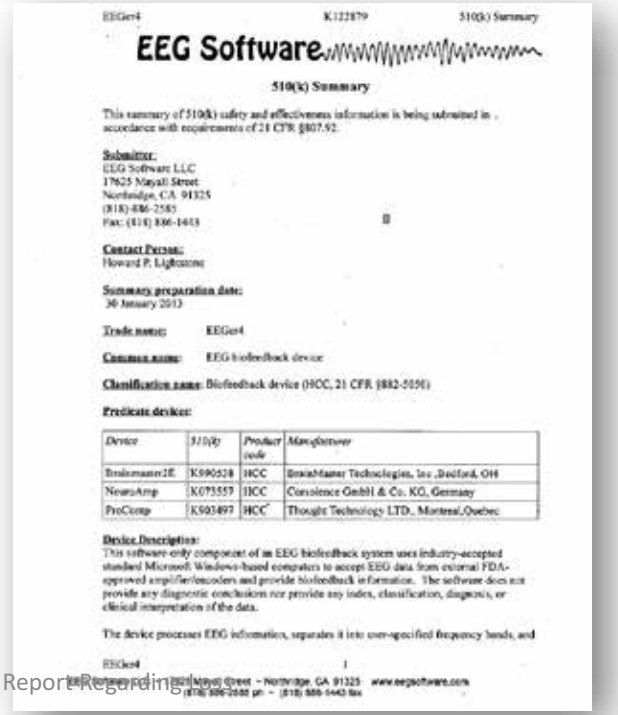
The VX3 is a lightweight, compact, digital Holter recorder designed for the recording of ECG data collected from ambulatory patients. A derivative of the Datrix DR512 digital Holter recorder, the VX3 has enhanced features, including an LCD to verify leadwire hookup and display recorder status and error messages, optional keypad for selection of various options, and optional pacemaker pulse detection. Various channel and lead configurations are accommodated by using the appropriate leadwire set without additional recorder reconfiguration. Data are recorded on industry standard compact flashcards for subsequent download and to a Holter playback system. Sampling rates are factory programmable to accommodate compatibility with various OEM Holter playback systems.

Intended Use

The VX3 digital Holter recorder is intended for the recording of ECG data collected from ambulatory patients. The recorder can collect data in the presence of implanted pacemaker pulses, and can detect and record the occurrence of signals characteristic of pacemaker pulses. The recorder is used under the order of a physician, who reviews the data after downloading and processing by a Holter playback system. The physician determines the presence of normal and abnormal ECG data as well as pacemaker pulses during the events of the patient's daily activity.

Sample rate: 128 to 512 per channel/sec. programmable

Bandwidth: 0.05Hz to 50 Hz



EEGer4 K122879 510(k) Summary

EEG Software

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR §807.92.

Submitter:
EEG Software LLC
17925 Nayall Street
Northridge, CA 91325
(818)-886-2585
Fax: (818) 886-1413

Contact Person:
Howard P. Lightstone

Summary preparation date:
30 January 2013

Trade name: EEGer4

Common name: EEG biofeedback device

Classification name: Biofeedback device (HCC, 21 CFR §882.5050)

Predicate devices:

Device	510(k)	Product code	Manufacturer
Brainmaster2E	K990528	HCC	Brainmaster Technologies, Inc ,Bedford, OH
NeuroAmp	K073557	HCC	Conviviance GmbH & Co. KG, Germany
ProComp	K903497	HCC	Thought Technology LTD., Montreal,Quebec

Device Description:
This software-only component of an EEG biofeedback system uses industry-accepted standard Microsoft Windows-based computers to accept EEG data from external FDA-approved amplifier/encoders and provide biofeedback information. The software does not provide any diagnostic conclusions nor provide any index, classification, diagnosis, or clinical interpretation of the data.

The device processes EEG information, separates it into user-specified frequency bands, and

EEGer4 1

EEG Software, 9825 Nayall Street – Northridge, CA 91325 www.eegsoftware.com (818) 886-2585 ph – (818) 886-1443 fax

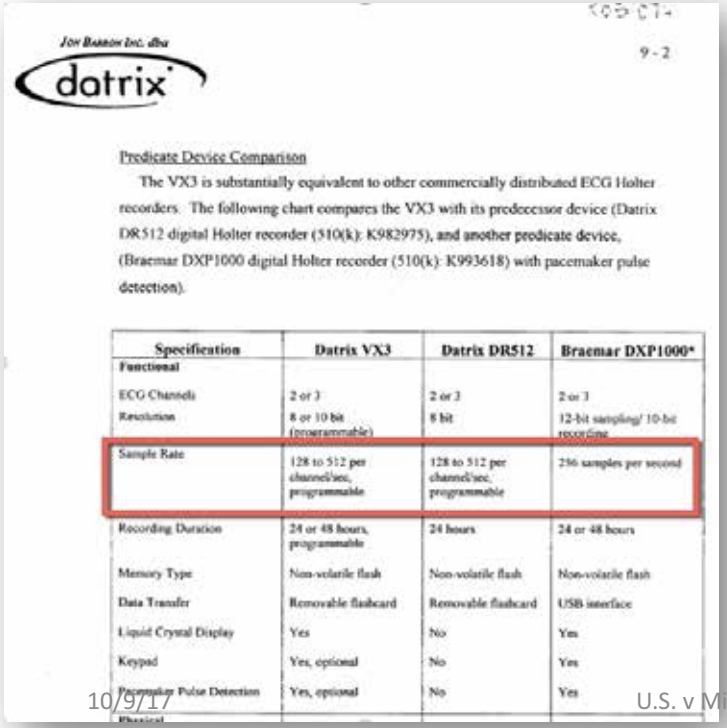
Sample rate: 256 (in range between the 128 and 512 of Datrix)

Bandwidth: 0.0Hz to 50 Hz

App. 308

Datrix 512 Uses Same Frequency as FDA Approved Device for EEGs

- Findings: Datrix 512 uses same frequency for ECG as other devices that do EEG



Jon Barron Inc. dba datrix

9 - 2

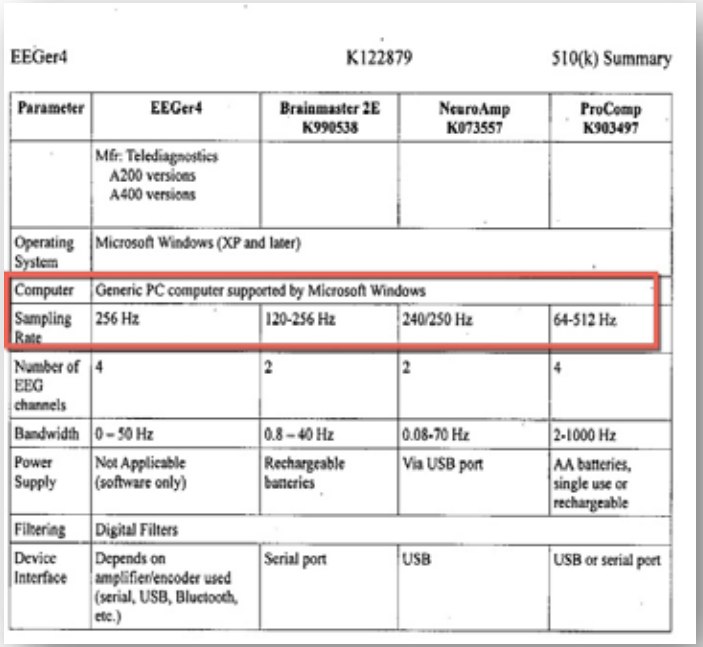
Predicate Device Comparison

The VX3 is substantially equivalent to other commercially distributed ECG Holter recorders. The following chart compares the VX3 with its predecessor device (Datrix DR512 digital Holter recorder (510(k): K982975), and another predicate device, (Braemar DXP1000 digital Holter recorder (510(k): K993618) with pacemaker pulse detection).

Specification	Datrix VX3	Datrix DR512	Braemar DXP1000*
Functional			
ECG Channels	2 or 3	2 or 3	2 or 3
Resolution	8 or 10 bit (programmable)	8 bit	12-bit sampling/ 10-bit recording
Sample Rate	128 to 512 per channel/sec, programmable	128 to 512 per channel/sec, programmable	256 samples per second
Recording Duration	24 or 48 hours, programmable	24 hours	24 or 48 hours
Memory Type	Non-volatile flash	Non-volatile flash	Non-volatile flash
Data Transfer	Removable flashcard	Removable flashcard	USB interface
Liquid Crystal Display	Yes	No	Yes
Keypad	Yes, optional	No	Yes
Pacemaker Pulse Detection	Yes, optional	No	Yes
Physical			

Sample rate: 128 to 512 per channel/sec. programmable

Bandwidth: 0.05Hz to 50 Hz



EEGer4 K122879 510(k) Summary

Parameter	EEGer4	Brainmaster 2E K990538	NeuroAmp K073557	ProComp K903497
	Mfr: Telediagnostics A200 versions A400 versions			
Operating System	Microsoft Windows (XP and later)			
Computer	Generic PC computer supported by Microsoft Windows			
Sampling Rate	256 Hz	120-256 Hz	240/250 Hz	64-512 Hz
Number of EEG channels	4	2	2	4
Bandwidth	0 – 50 Hz	0.8 – 40 Hz	0.08-70 Hz	2-1000 Hz
Power Supply	Not Applicable (software only)	Rechargeable batteries	Via USB port	AA batteries, single use or rechargeable
Filtering	Digital Filters			
Device Interface	Depends on amplifier/encoder used (serial, USB, Bluetooth, etc.)	Serial port	USB	USB or serial port

Sample rate: 256 (in range between the 128 and 512 of Datrix)

Bandwidth: 0.0Hz to 50 Hz

App. 309

To Establish the Government's Case that there is Fraud, a Complete Review would be Required

- Treatment
- Payment
- Health Care Operations

https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/disclosures-treatment-payment-health-care-operations/index.html

HIPAA Definition at 45 CFR 164.501.

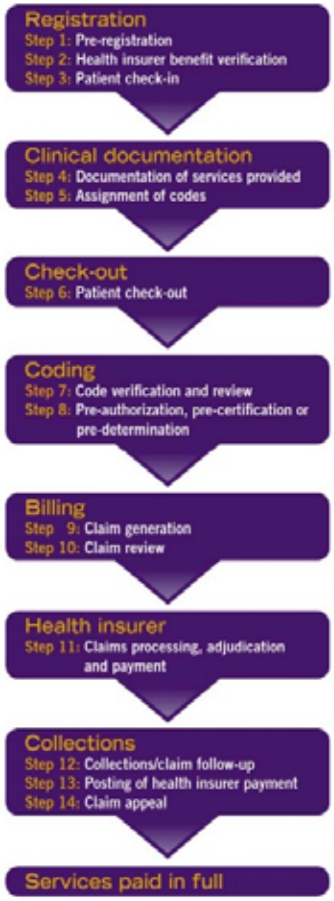
- "Treatment" generally means the provision, coordination, or management of health care and related services among health care providers or by a health care provider with a third party, consultation between health care providers regarding a patient, or the referral of a patient from one health care provider to another.

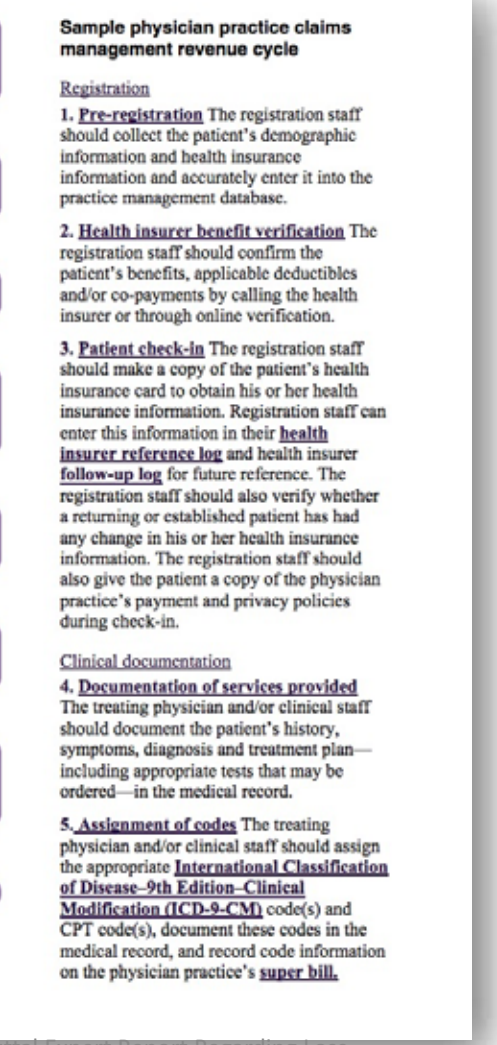
42 CFR 405.902 - Definitions.

- *Clean claim* means a claim that has no defect or impropriety (including any lack of required substantiating documentation) or particular circumstance requiring special treatment that prevents timely payment from being made on the claim under title XVIII within the time periods specified in sections 1816(c) and 1842(c) of the Act.

American Medical Association:

Fourteen (14) step process to get paid for providing medical services





Sample physician practice claims management revenue cycle

Registration

1. **Pre-registration** The registration staff should collect the patient's demographic information and health insurance information and accurately enter it into the practice management database.

2. **Health insurer benefit verification** The registration staff should confirm the patient's benefits, applicable deductibles and/or co-payments by calling the health insurer or through online verification.

3. **Patient check-in** The registration staff should make a copy of the patient's health insurance card to obtain his or her health insurance information. Registration staff can enter this information in their **health insurer reference log** and health insurer **follow-up log** for future reference. The registration staff should also verify whether a returning or established patient has had any change in his or her health insurance information. The registration staff should also give the patient a copy of the physician practice's payment and privacy policies during check-in.

Clinical documentation

4. **Documentation of services provided** The treating physician and/or clinical staff should document the patient's history, symptoms, diagnosis and treatment plan—including appropriate tests that may be ordered—in the medical record.

5. **Assignment of codes** The treating physician and/or clinical staff should assign the appropriate **International Classification of Disease–9th Edition–Clinical Modification (ICD-9-CM)** code(s) and CPT code(s), document these codes in the medical record, and record code information on the physician practice's **super bill.**

Relevance?

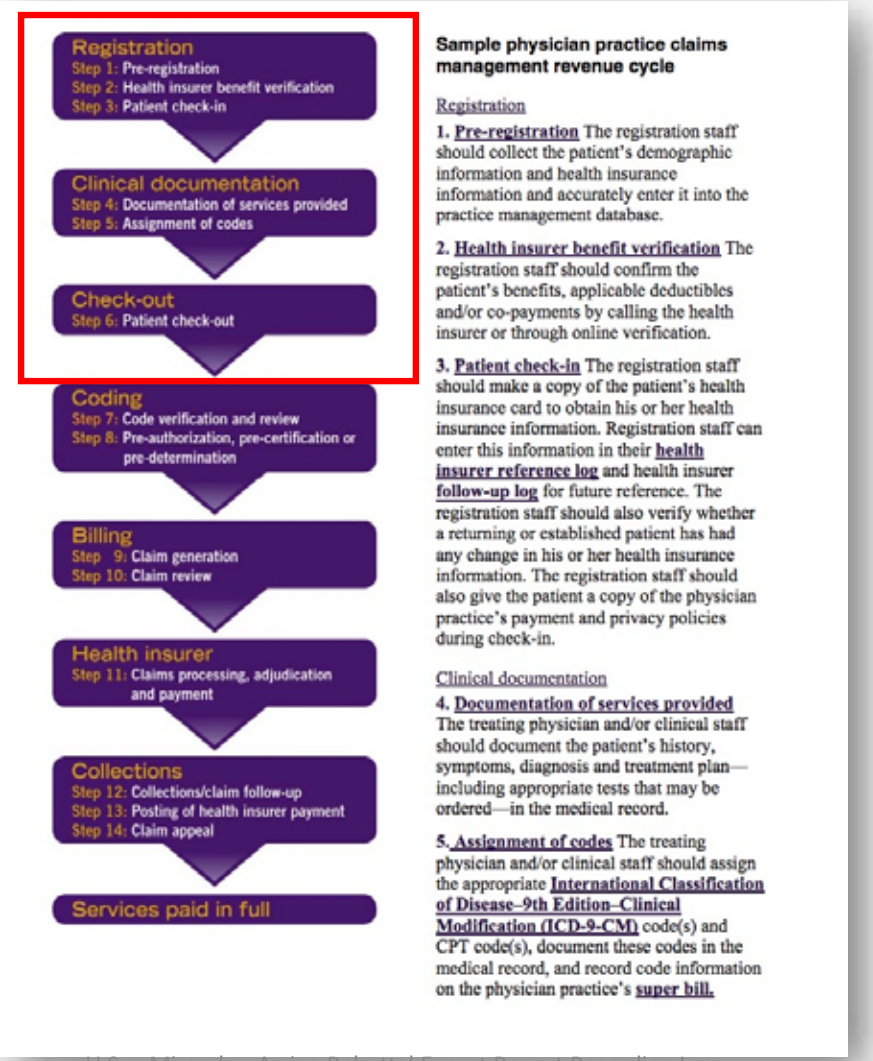
ALL of this information is necessary to determine veracity of a claim

Source: American Medical Association, "Prepare that Claim, taking an active approach to the claims management cycle"

App. 313

Why is this relevant from a fraud perspective?

1. Verify that the identity of the patient
2. Verify that provider intended to render services and bill insurance
3. Verify that the patient appeared for treatment
4. Documentation of the service is what insurance companies use to verify the validity of a claim
5. Assignment of codes indicates which specific services were provided



Source: American Medical Association, "Prepare that Claim, taking an active approach to the claims management cycle"

Provided by the Government?

Step 1: **no**

Step 2: **no**

Step 3: **no**

Step 4: **no**

Step 5: **no**

Step 6: **no**

Step 7: **no**

Step 8: **no**

Step 9: **partial**

Step 10: **no**

Step 11: **partial**

Step 12: no

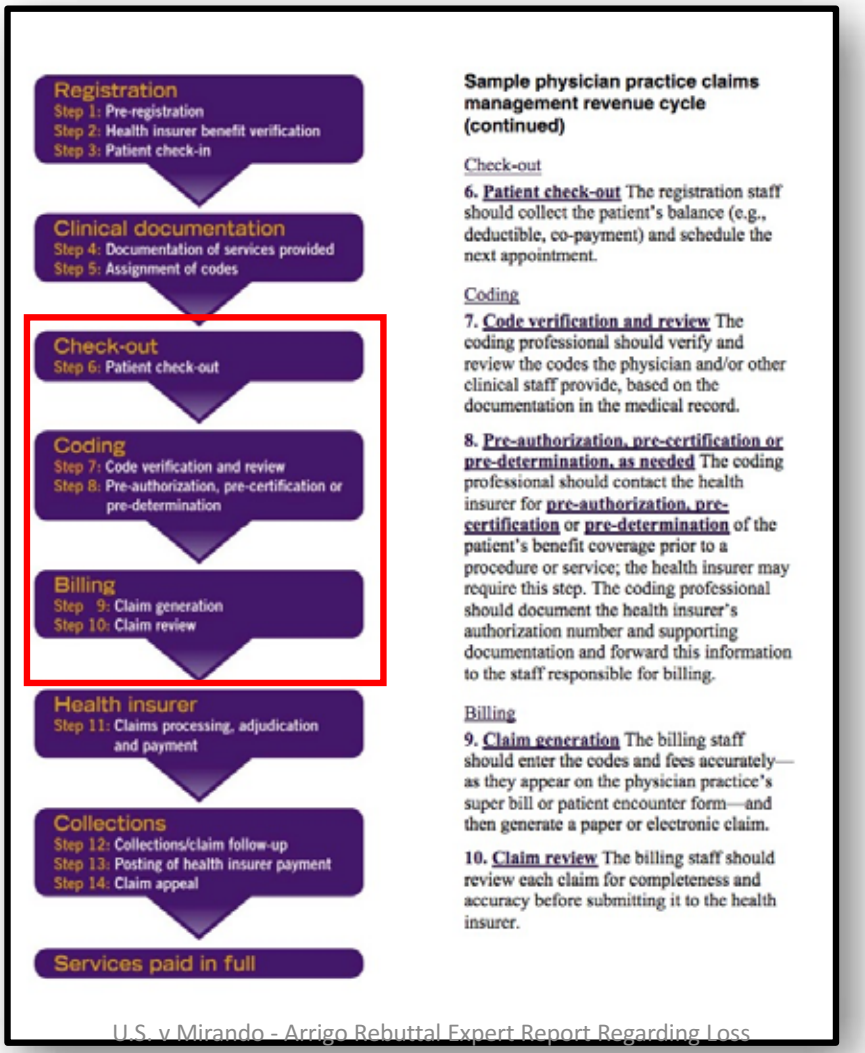
Step 13: **partial**

Step 14: **partial**

(4 appeals were available out of 31,471 claims)

Why is this relevant from a fraud perspective?

6. Verify that the provider collected from patient for services
7. Verify that correct codes were used that accurately reflect the diagnosis and procedures; essential for determining medical necessity in any audit
8. Verify post delivery of services that the benefit coverage is there and that billing has correct data
9. Verify that the claim was generated and basis for pricing information from the bill
10. Verify claim for completeness and accuracy before submission



Source: American Medical Association, "Prepare that Claim, taking an active approach to the claims management cycle"

Provided by the Government?

Step 1: **no**

Step 2: **no**

Step 3: **no**

Step 4: **no**

Step 5: **no**

Step 6: **no**

Step 7: **no**

Step 8: **no**

Step 9: **partial**

Step 10: **no**

Step 11: **partial**

Step 12: no

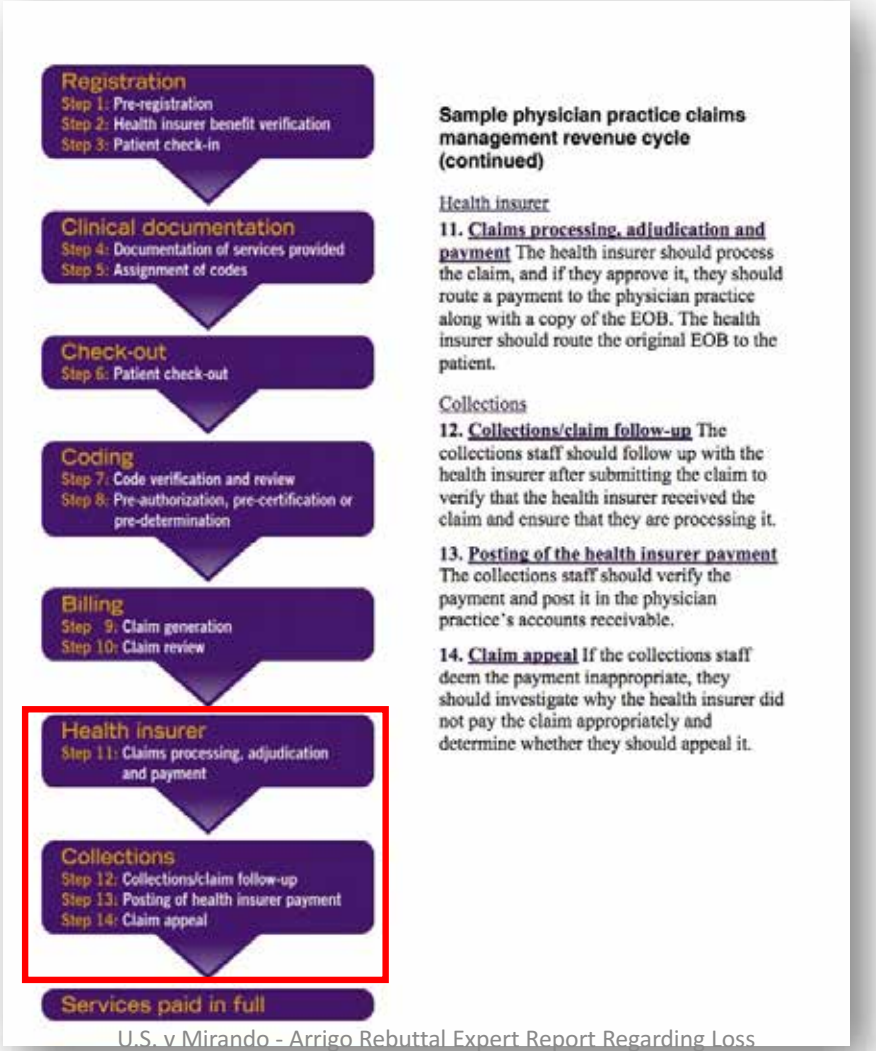
Step 13: **partial**

Step 14: **partial**

(4 appeals were available out of 31,471 claims)

Why is this relevant from a fraud perspective?

11. Verify that the claim was paid via Explanation of Benefits (EOB) including exact services provided, patient diagnosis, date of service.
12. Verify claim receipt either manually or electronically (if not received, cannot be a valid claim)
13. Verify that the claim was paid
14. Verify the appeal process, if any and results of the appeal.



Source: American Medical Association, "Prepare that Claim, taking an active approach to the claims management cycle"

Provided by the Government?

Step 1: **no**

Step 2: **no**

Step 3: **no**

Step 4: **no**

Step 5: **no**

Step 6: **no**

Step 7: **no**

Step 8: **no**

Step 9: **partial**

Step 10: **no**

Step 11: **partial**

Step 12: no

Step 13: **partial**

Step 14: **partial**

(4 appeals were available out of 31,471 claims)

In the absence of the 14 complete steps, I was left to assess the Government's methods using only <u>partial information</u> for Steps 9, 11, 13, 14

 10

<u>Provided by the Government?</u>

Step 1: **no**

Step 2: **no**

Step 3: **no**

Step 4: **no**

Step 5: **no**

Step 6: **no**

Step 7: **no**

Step 8: **no**

Step 9: **partial**

Step 10: **no**

Step 11: **partial**

Step 12: no

Step 13: **partial**

Step 14: **partial**

(4 appeals were available

out of 31,471 claims)

App. 317

United States v. Siddiqi, 959 F.2d 1167 (2nd Cir. 1992).

- A New York physician was recently acquitted on 72 counts in a case in which no one -- including the government -- knew exactly what medical service a particular billing code covered, thus supporting the defendant's contention that he believed his claims were proper and that he did not *knowingly and willfully* submit false claims.

https://www.nacdl.org/CHAMPION/ARTICLES/94sep01.htm

United States v. Kline

- the court held that it was improper to instruct the jury on the government's aiding and abetting theory under 18 U.S.C. 2, and reversed the defendant's convictions.
- The defendant was charged with violating the False Claims Act by making and submitting fraudulent claims, but the government was unable to prove that it was the defendant who prepared and submitted the claims.
- To cure this evidentiary defect, the prosecution tendered and the court gave an instruction that the defendant could be convicted for aiding another employee in submitting the false claims. However, that employee testified that she probably made a mistake in submitting the claims, which she said was easy to do given the complex billing codes.
- The aiding and abetting statute, 18 U.S.C. 2, has two parts, the court held. The first requires the existence of a principal who was aided by the defendant; here, the court said, there is no evidence of a principal. The second part of 18 U.S.C. 2 punishes a defendant who causes a criminal act to be done by another; however, the indictment only charged that the defendant "made and presented" the false claims, and the Court held that the government was, therefore, not entitled to the instruction.

https://www.nacdl.org/CHAMPION/ARTICLES/94sep01.htm

May 13, 2015 Email from Crowley to his Attorney

Better yet before Holter labs started Mike worked for INTEL and knew NOTHING of the cardiac monitoring business yet Stan has worked in this business his entire life, so obviously Stan brought Mike into this field of business.

* “Mike” is Mr. Michael Mirando in the email above

App. 320

Is it possible Records were altered by Jim Cast?

From: Michael Mirando [mailto:mike@holterlabs.com]
Sent: Thursday, November 1, 2012 11:41 AM
To: Joseph M. Preis <jpreis@gaplegal.com>
Cc: mike@holterlabs.com
Subject: Jim Cast Website Hacking

Hey,

I just called Blue Shield of CA they said that the account was altered on 10/18/2012… I have not logged into this site in over six months so I know that it was him as Stan does not ever log into this account… I captured a screen shot of what I saw on my screen; see attached…

E-Mail Used: holterlabsllc@gmail.com (This is the e-mail that Jim Cast created as I do not own this e-mail address nor does Stan)

Security Question: Fathers Middle Name: Dale (I believe that his father's middle name)

Hope this helps… Computer Crime…? Gaining access on a false pretenses being he is not part of the company…?

I have since changed all of the other information so that he will not be able to access this again…

Thanks,

Michael Mirando

From: Michael Mirando [mailto:mike@holterlabs.com]
Sent: Tuesday, February 12, 2013 10:26 AM
To: Joseph M. Preis <jpreis@gaplegal.com>
Cc: mike@holterlabs.com
Subject: Jim Cast Illegal Logon

Joe,

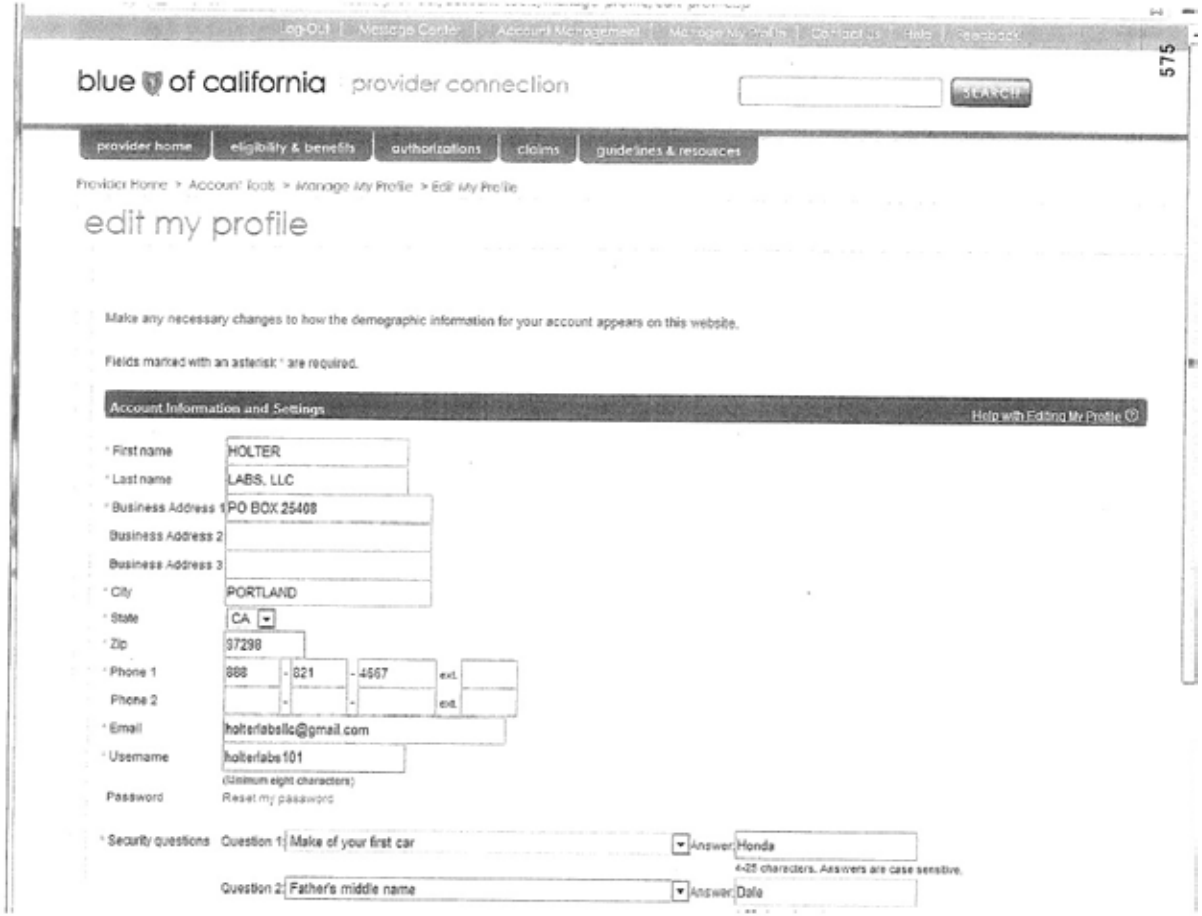
See attached… Jim Cast illegally created an account on "NaviNet" as site that allows users to view private data as it pertains to Health Care claims… He has now Hacked in to Blue Cross\Blue Shield and NaviNet posing as an owner of Holter Labs… You can under "Security Officer" that its states "Yes"… His account is now terminated… The staff sent me this screen shot per my request…

Hope this helps…

Thanks,

Michael Mirando
Holter Labs, LLC

Phone: 888-821-4667
E-Mail: mike@holterlabs.com
Web: www.HolterLabs.com



blue of california provider connection

SEARCH

575

provider home | eligibility & benefits | authorizations | claims | guidelines & resources

Provider Home > Account Tools > Manage My Profile > Edit My Profile

edit my profile

Make any necessary changes to how the demographic information for your account appears on this website.

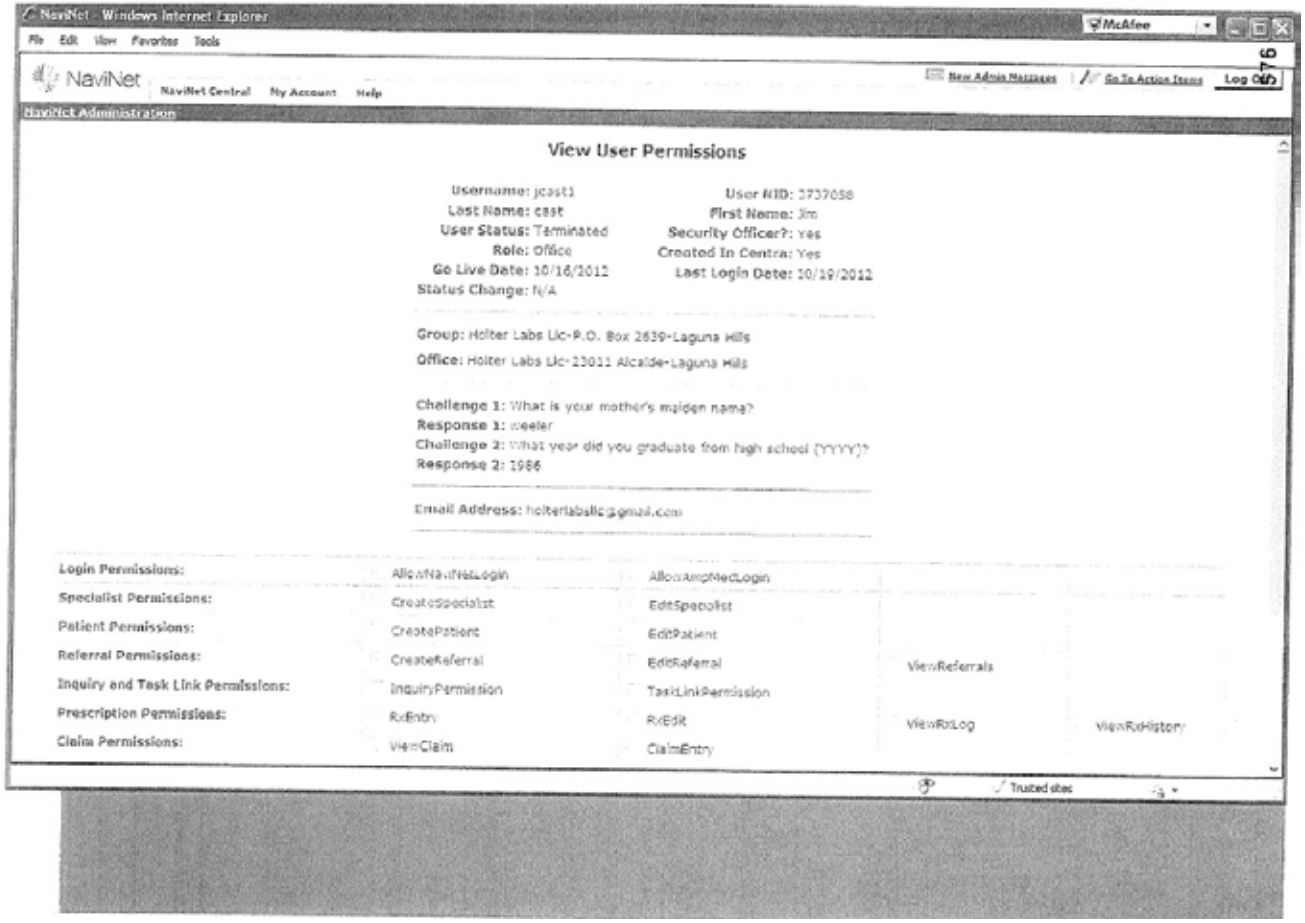
Fields marked with an asterisk * are required.

Account Information and Settings — Help with Editing My Profile

* First name	HOLTER
* Last name	LABS, LLC
* Business Address 1	PO BOX 25468
Business Address 2	
Business Address 3	
* City	PORTLAND
* State	CA
* Zip	37298
* Phone 1	888 - 821 - 4567 ext.
Phone 2	- - ext.
* Email	holterlabsllc@gmail.com
* Username	holterlabs101 (Minimum eight characters)
Password	Reset my password
* Security questions	Question 1: Make of your first car — Answer: Honda
	Question 2: Father's middle name — Answer: Dale

4-25 characters. Answers are case sensitive.

App. 323


NaviNet - Windows Internet Explorer
NaviNet
NaviNet Central
My Account
Help
NaviNet Administration
View User Permissions
Username: jcast1
Last Name: cast
User Status: Terminated
Role: Office
Go Live Date: 10/16/2012
Status Change: N/A
User NID: 3737058
First Name: Jim
Security Officer?: Yes
Created In Centra: Yes
Last Login Date: 10/19/2012
Group: Holter Labs Llc-P.O. Box 2639-Laguna Hills
Office: Holter Labs Llc-23011 Alcalde-Laguna Hills
Challenge 1: What is your mother's maiden name?
Response 1: weeler
Challenge 2: What year did you graduate from high school (YYYY)?
Response 2: 1986
Email Address: holterlabsllc@gmail.com
Login Permissions:
Specialist Permissions:
Patient Permissions:
Referral Permissions:
Inquiry and Task Link Permissions:
Prescription Permissions:
Claim Permissions:
CreateSpecialist
EditSpecialist
CreatePatient
EditPatient
CreateReferral
EditReferral
ViewReferrals
InquiryPermission
TaskLinkPermission
RxEntry
RxEdit
ViewRxLog
ViewRxHistory
ViewClaim
ClaimEntry

App. 324

Government's Case

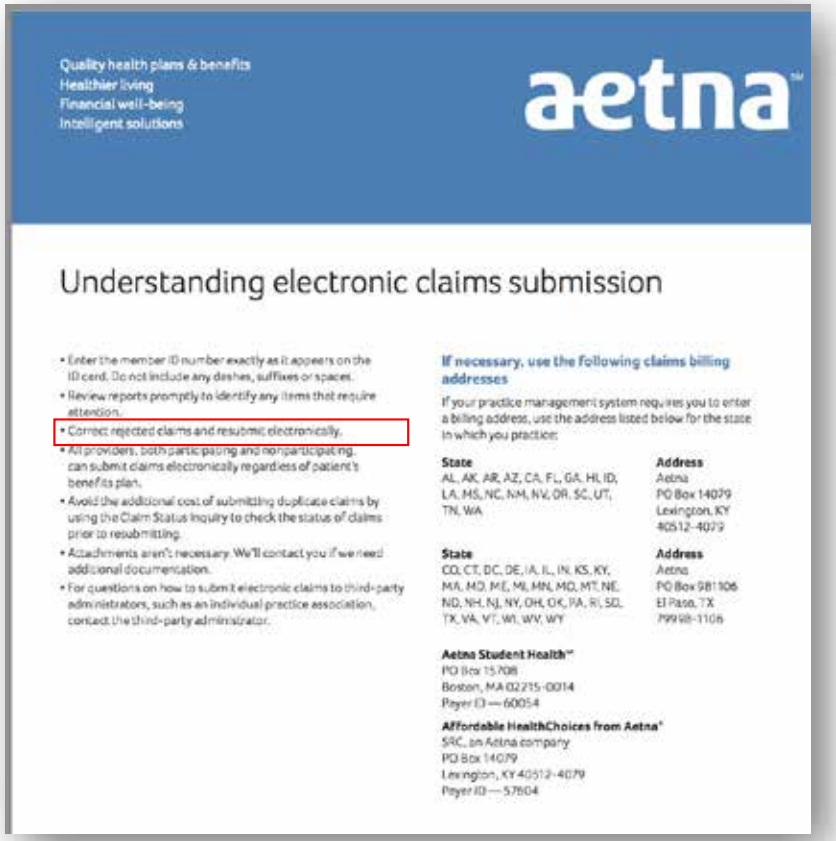
- Limited statistical sampling of < 10 patients and extrapolation to thousands of claims
- Lack of notice of guidelines by Medicare led to **no audits**
- Lack of notice of guidelines by private insurance led to **no audits**
- Arguing presumptions that favor the Government using health plan policies (Aetna) designed to unreasonably deny claims, paid by others, and
- Government ignores that Offsetting any alleged overpayment with the existence of underpayments or non payments

Government's Patient Interviews Are Limited in Sample Size

- There are over 3,351 Aetna claims line items in Government's data produced
- There are six patient interviews and two (2) are related to Aetna with supporting detail
- Only six patients were interviewed
  - Belen Perazzo
  - Bennett
  - Hattrup
  - Lisa Meza – Aetna (not mentioned in Governments' summary of Evidence)
  - Lisa Solmor - Aetna
  - Maria Landis
  - Foster – "appears to be valid," not paid

Based on my knowledge training, education and experience and prior expert work for IDTFs, it is my opinion that Aetna has a history of denying claims that other insurance pays for ECG and EEG using "experimental" reason for denial

Aetna Policy Assumes Some Claims are Duplicated



Quality health plans & benefits
Healthier living
Financial well-being
Intelligent solutions

aetna

Understanding electronic claims submission

- Enter the member ID number exactly as it appears on the ID card. Do not include any dashes, suffixes or spaces.
- Review reports promptly to identify any items that require attention.
- Correct rejected claims and resubmit electronically.
- All providers, both participating and nonparticipating, can submit claims electronically regardless of patient's benefits plan.
- Avoid the additional cost of submitting duplicate claims by using the Claim Status Inquiry to check the status of claims prior to resubmitting.
- Attachments aren't necessary. We'll contact you if we need additional documentation.
- For questions on how to submit electronic claims to third-party administrators, such as an individual practice association, contact the third-party administrator.

If necessary, use the following claims billing addresses

If your practice management system requires you to enter a billing address, use the address listed below for the state in which you practice:

State	Address
AL, AK, AR, AZ, CA, FL, GA, HI, ID, LA, MS, NC, NM, NV, OR, SC, UT, TN, WA	Aetna PO Box 14079 Lexington, KY 40512-4079
CO, CT, DC, DE, IA, IL, IN, KS, KY, MA, MD, ME, MI, MN, MO, MT, NE, ND, NH, NJ, NY, OH, OK, PA, RI, SD, TX, VA, VT, WI, WV, WY	Aetna PO Box 981106 El Paso, TX 79998-1106

Aetna Student Health℠
PO Box 15708
Boston, MA 02215-0014
Payer ID — 60054

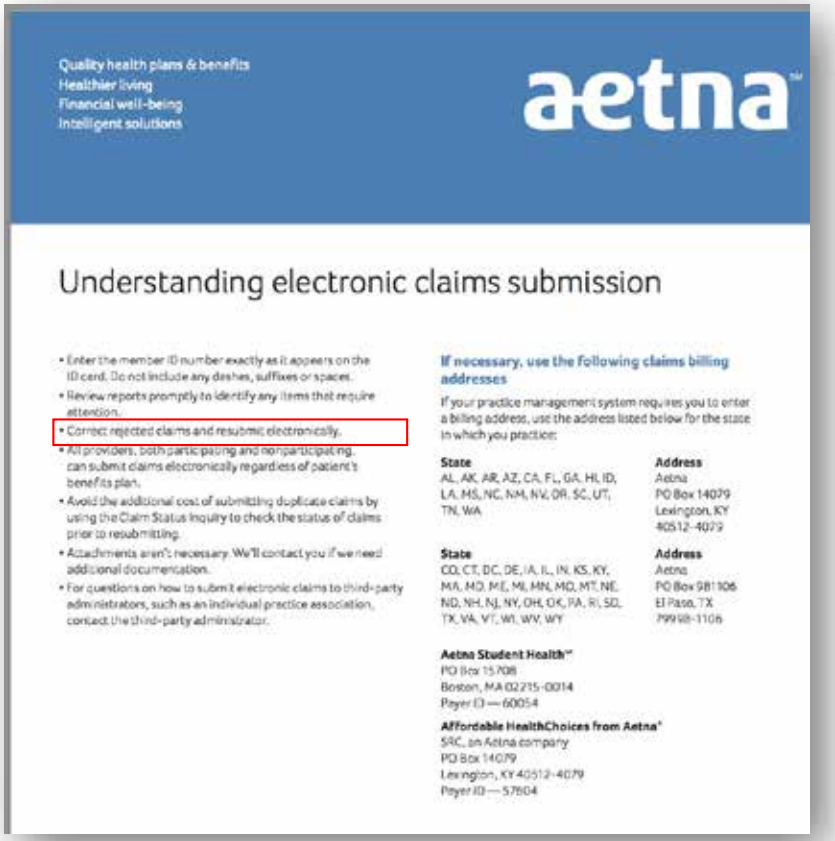
Affordable HealthChoices from Aetna®
SRC, an Aetna company
PO Box 14079
Lexington, KY 40512-4079
Payer ID — 57604

- Correct rejected claims and **resubmit** electronically.
- Avoid the additional cost of **submitting duplicate** claims by using the Claim Status Inquiry to **check the status** of claims prior to resubmitting.
- Attachments aren't necessary. We'll contact you if we need additional documentation.

Source: Aetna 23.03.892.1 B (5/13)

App. 327

Aetna Policy Assumes No Documentation to Support Claim is Necessary, UNLESS there is an audit



Quality health plans & benefits
Healthier living
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aetna

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State	Address
AL, AK, AR, AZ, CA, FL, GA, HI, ID, LA, MS, NC, NM, NV, OR, SC, UT, TN, WA	Aetna PO Box 14079 Lexington, KY 40512-4079
CO, CT, DC, DE, IA, IL, IN, KS, KY, MA, MD, ME, MI, MN, MO, MT, NE, ND, NH, NJ, NY, OH, OK, PA, RI, SD, TX, VA, VT, WI, WV, WY	Aetna PO Box 981106 El Paso, TX 79998-1106

Aetna Student Health℠
PO Box 15708
Boston, MA 02215-0014
Payer ID — 60054

Affordable HealthChoices from Aetna®
SRC, an Aetna company
PO Box 14079
Lexington, KY 40512-4079
Payer ID — 57604

- "Attachments aren't necessary. We'll contact you if we need additional documentation. "

Source: Aetna 23.03.892.1 B (5/13)

App. 328

What Happened in Holter Labs Case?

- Duplicate claims were submitted
  - Unknown by who
  - Unknown for what reason
  - Only one claim was paid
- NO audits were performed
- NO determinations were made

Unclear if Duplicates were intentional fraud or claim status checks that led to unintentional redundancy

Government's Patient Interviews Do Not Conclusively Demonstrate Fraud Because Patient's Recollection May be Inaccurate, or documentation in interview may not completely address factual basis for coding and billing

- Patients were interviewed up to four (4) years after treatment
- Is there certainty that these patients remembered exactly what services were provided to them?

- Example:
  - Patient xx states "only had ECG one time"
  - Does "one time" mean one day or one episode spanning multiple days?
- Single day vs. episode is important because it establishes:
  - Whether a service was provided for and billed on a single day
  - Whether a service was provided for multiple days (>24 hour period)

Independent Diagnostic Testing Facility (IDTF) Filings

Tracking ID: T060320140000969
Date: 06/09/2014

Authorized Official Certification Statement for Clinics and Group Practices

These are additional requirements that the supplier must meet and maintain to bill the Medicare program. By signing, the supplier is attesting to have read the requirements and understanding them.

By his/her signature(s), the authorized official named below agrees to adhere to the following requirements stated in this Certification Statement:

1) I authorize the Medicare contractor to verify the information contained herein. I agree to notify the Medicare contractor of any future change to the information contained in this application in accordance with provisions found at 42 CFR 424.516. I understand that any change in business structure of this supplier may require the submission of a new application.

2) I have read and understand the Penalties for Falsifying Information as printed in this application. I understand that any deliberate omission, misrepresentation, or falsification of any information contained in this application or contained in any communication supplying information to Medicare, or any deliberate alteration of text on this application form, may be punished by criminal, civil, or administrative penalties including, but not limited to, the denial or revocation of Medicare identification number(s), and/or the imposition of fines, civil damages, and/or imprisonment.

3) I agree to abide by the Medicare laws, regulations and program instructions that apply to this supplier. The Medicare laws, regulations and program instructions are available through the Medicare contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark Law), and on the supplier's compliance with all applicable conditions of participation in Medicare.

4) Neither this supplier, nor any 5 percent or greater owner, partner, officer, director, managing employee, authorized official, or delegated official is currently sanctioned, suspended, debarred, or excluded by the Medicare or State Health Care Program, e.g., Medicaid program, or any other Federal program, or is otherwise prohibited from supplying services to Medicare or other Federal program beneficiaries.

5) I agree that any existing or future overpayment made to the supplier by the Medicare program may be recouped by Medicare through the withholding of future payments.

6) I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and I will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity.

7) I authorize any national accrediting body whose standards are recognized by the Secretary as meeting the Medicare program participation requirements, to release to any authorized representative, employee, or agent of the CMS, a copy of my most recent accreditation survey, together with any information related to the survey that CMS may require (including corrective action plans).

PART V: AUTHORIZATION

I hereby authorize the Centers for Medicare & Medicaid Services (CMS) to initiate credit entries, and in accordance with 31 CFR part 210.6(f) initiate adjustments for any credit entries made in error to the account indicated above. I hereby authorize the financial institution/bank named above to credit and/or debit the same to such account. CMS may assign its rights and obligations under this agreement to CMS' designated fee-for-service contractor. CMS may change its designated contractor at CMS' discretion.

If payment is being made to an account controlled by a Chain Home Office, the Provider of Services hereby acknowledges that payment to the Chain Office under these circumstances is still considered payment to the Provider, and the Provider authorizes the forwarding of Medicare payments to the Chain Home Office.

If the account is drawn in the Physician's or Individual Practitioner's Name, or the Legal Business Name of the Provider/ Supplier, the said Provider or Supplier certifies that he/she has sole control of the account referenced above, and certifies that all arrangements between the Financial Institution and the said Provider or Supplier are in accordance with all applicable Medicare regulations and instructions.

This authorization agreement is effective as of the signature date below and is to remain in full force and effect until CMS has received written notification from me of its termination in such time and such manner as to afford CMS and the Financial Institution a reasonable opportunity to act on it. CMS will continue to send the direct deposit to the Financial Institution indicated above until notified by me that I wish to change the Financial Institution receiving the direct deposit. If my Financial Institution information changes, I agree to submit to CMS an updated EFT Authorization Agreement.

SIGNATURE LINE

ORIGINAL SIGNATURE

Authorized/Delegated Official Name (Print)	Authorized/Delegated Official Telephone Number
MICHAEL MIRANDO	888-821-4667
Authorized/Delegated Official Title	**Authorized/Delegated Official E-mail Address**
OWNER	MIKE@HOLTERLABS.COM
Authorized/Delegated Official Signature *(Note: Must be original signature in black or blue ink)*	**Date**
	6/9/2014

PRIVACY ACT ADVISORY STATEMENT

Sections 1842, 1862(b) and 1874 of title XVIII of the Social Security Act authorize the collection of this information. The purpose of collecting this information is to authorize electronic funds transfers.

Per 42 CFR 424.510(e)(1), providers and suppliers are required to receive electronic funds transfer (EFT) at the time of enrollment, revalidation, change of Medicare contractors or submission of an enrollment change request; and (2) submit the CMS-588 form to receive Medicare payment via electronic funds transfer.

The information collected will be entered into system No. 09-70-0501, titled "Carrier Medicare Claims Records," and No. 09-70-0503, titled "Intermediary Medicare Claims Records" published in the Federal Register Privacy Act Issuances, 1991 Comp. Vol. 1, pages 419 and 424, or as updated and republished. Disclosures of information from this system can be found in this notice.

You should be aware that P.L. 100-503, the Computer Matching and Privacy Protection Act of 1988, permits the government, under certain circumstances, to verify the information you provide by way of computer matches.

All supervising physician(s) rendering supervisory services for this IDTF must sign and date this section. All signatures must be original.

1. I hereby acknowledge that I have agreed to provide (IDTF Name) **Holter Labs** with the identified Supervisory Physician services for all CPT-4 and HCPCS codes reported in the submitted enrollment application associated to the above Tracking ID. (See section 2 of this document if all reported CPT-4 and HCPCS codes do not apply). I also hereby certify that I have the required proficiency in the performance and interpretation of each type of diagnostic procedure, as reported by CPT-4 or HCPCS code in the submitted enrollment application associated to the above Tracking ID (except for those CPT-4 or HCPCS codes identified in section 2 of this document). I have read and understand the Penalties for Falsifying Information as printed in the submitted application. I am aware that falsifying information may result in fines and/or imprisonment. If I undertake supervisory responsibility at any additional IDTFs, I understand that it is my responsibility to notify this IDTF at that time.

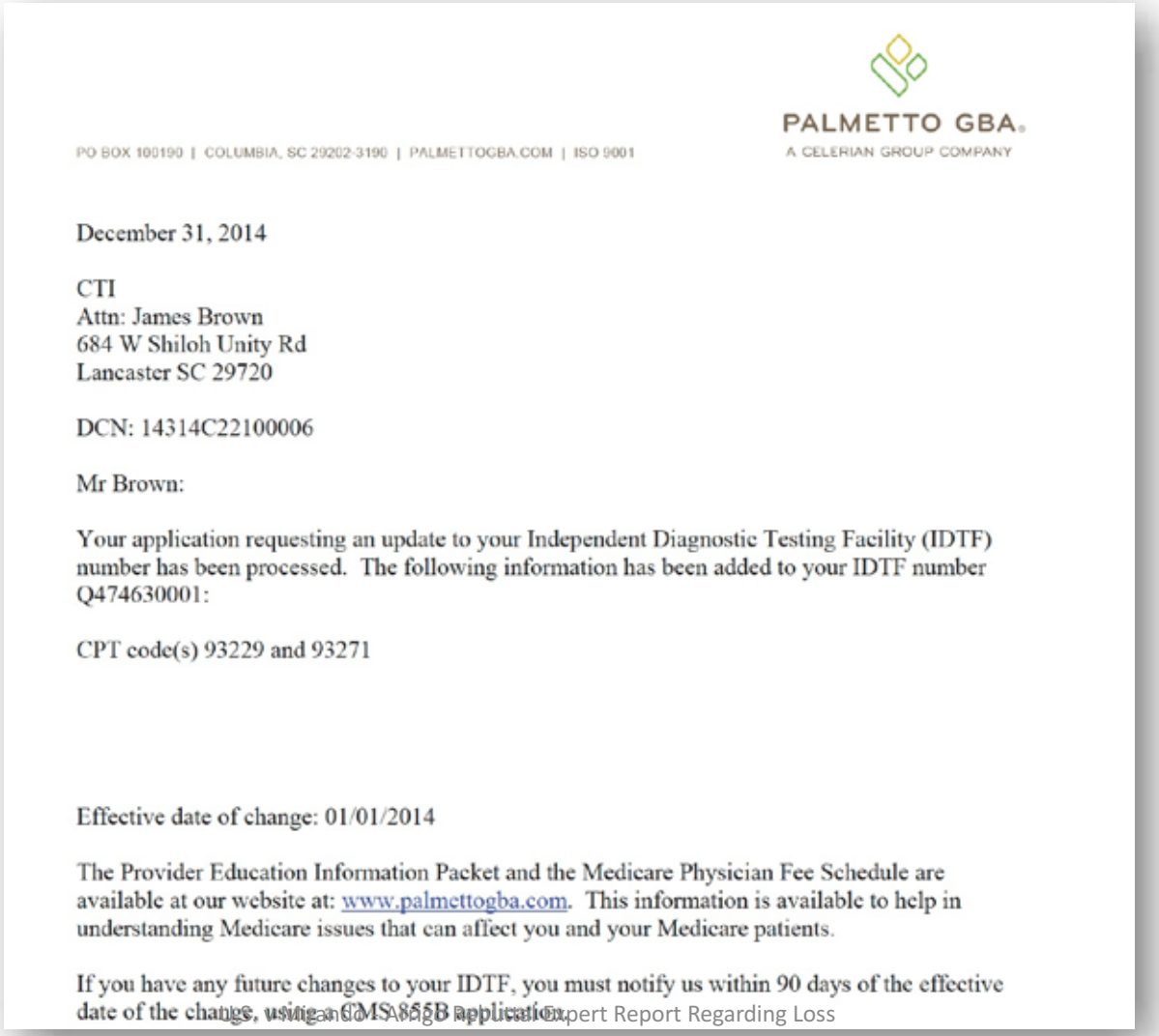
2. I am not acting as a supervising physician for the following CPT-4 and/or HCPCS codes reported in this Attachment.

CPT-4 or HCPCS Code	CPT-4 or HCPCS Code	CPT-4 or HCPCS Code
93726		
93925		
93278		

Supervising Physician:
Sudesh Kedar
(803) 285-2225

IGINAL SIGNATURE

Signature of Supervising Physician — Date Signed (mm/dd/yyyy): 6/10/2014



PALMETTO GBA
A CELERIAN GROUP COMPANY

PO BOX 100190 | COLUMBIA, SC 29202-3190 | PALMETTOGBA.COM | ISO 9001

December 31, 2014

CTI
Attn: James Brown
684 W Shiloh Unity Rd
Lancaster SC 29720

DCN: 14314C22100006

Mr Brown:

Your application requesting an update to your Independent Diagnostic Testing Facility (IDTF) number has been processed. The following information has been added to your IDTF number Q474630001:

CPT code(s) 93229 and 93271

Effective date of change: 01/01/2014

The Provider Education Information Packet and the Medicare Physician Fee Schedule are available at our website at: www.palmettogba.com. This information is available to help in understanding Medicare issues that can affect you and your Medicare patients.

If you have any future changes to your IDTF, you must notify us within 90 days of the effective date of the change, using a CMS-855B application.

App. 335

From: Jim Brown [jim@cairdtech.com]
Sent: Monday, August 04, 2014 10:00 AM
To: MARTIN A SMITH; Michael Mirando
Subject: Re: DCN 14164023100305 Medicare Enrollment Application ADR

Andy,

I reviewed the document you sent and I believe a certified Internal Medicine Doctor should be able to be our supervising physician.
These are the CPT Codes we would be billing.

93226 - cardio or internal

93025 - cardio

95921 - electrodiagnostic medicine or neurophysiology

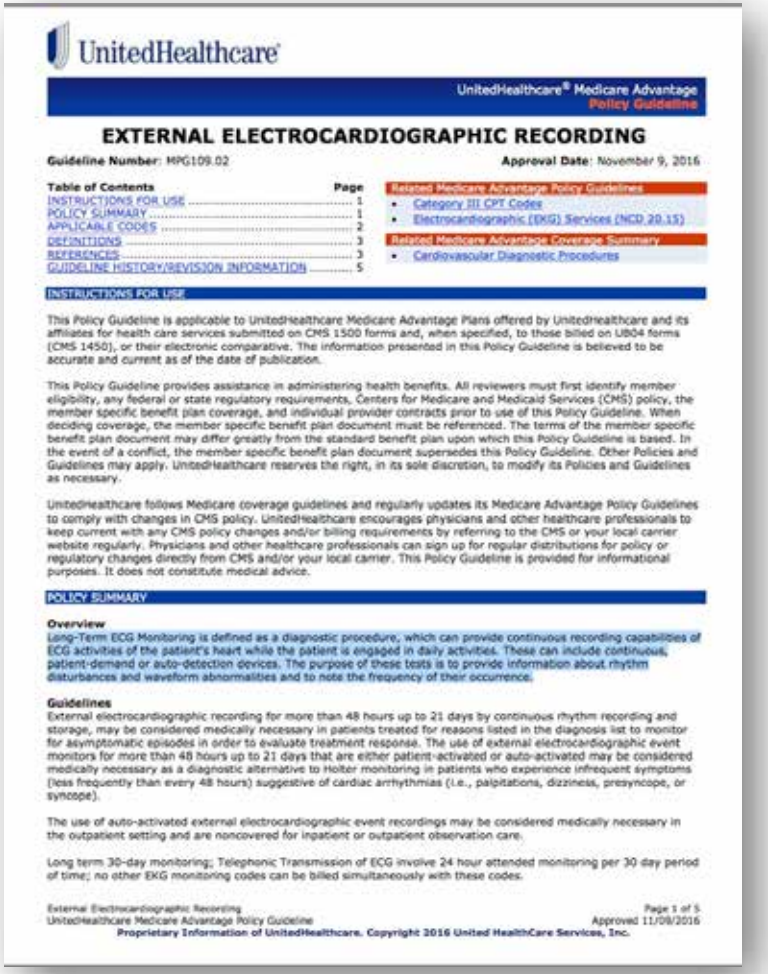
95806 - not a covered code for IDTF

93271 - cardio or internal

I want to make sure this is correct before we make an agreement with our physician.
Please let me know if this is correct.

Thanks,

Jim



UnitedHealthcare

UnitedHealthcare® Medicare Advantage
Policy Guideline

EXTERNAL ELECTROCARDIOGRAPHIC RECORDING

Guideline Number: MPG109.02 **Approval Date:** November 9, 2016

Table of Contents **Page**

Related Medicare Advantage Policy Guidelines
- Category III CPT Codes
- Electrocardiographic (EKG) Services (NCD 20.15)

Related Medicare Advantage Coverage Summary
- Cardiovascular Diagnostic Procedures

INSTRUCTIONS FOR USE

This Policy Guideline is applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates for health care services submitted on CMS 1500 forms and, when specified, to those billed on UB04 forms (CMS 1450), or their electronic comparative. The information presented in this Policy Guideline is believed to be accurate and current as of the date of publication.

This Policy Guideline provides assistance in administering health benefits. All reviewers must first identify member eligibility, any federal or state regulatory requirements, Centers for Medicare and Medicaid Services (CMS) policy, the member specific benefit plan coverage, and individual provider contracts prior to use of this Policy Guideline. When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document may differ greatly from the standard benefit plan upon which this Policy Guideline is based. In the event of a conflict, the member specific benefit plan document supersedes this Policy Guideline. Other Policies and Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary.

UnitedHealthcare follows Medicare coverage guidelines and regularly updates its Medicare Advantage Policy Guidelines to comply with changes in CMS policy. UnitedHealthcare encourages physicians and other healthcare professionals to keep current with any CMS policy changes and/or billing requirements by referring to the CMS or your local carrier website regularly. Physicians and other healthcare professionals can sign up for regular distributions for policy or regulatory changes directly from CMS and/or your local carrier. This Policy Guideline is provided for informational purposes. It does not constitute medical advice.

POLICY SUMMARY

Overview

Long-Term ECG Monitoring is defined as a diagnostic procedure, which can provide continuous recording capabilities of ECG activities of the patient's heart while the patient is engaged in daily activities. These can include continuous, patient-demand or auto-detection devices. The purpose of these tests is to provide information about rhythm disturbances and waveform abnormalities and to note the frequency of their occurrence.

Guidelines

External electrocardiographic recording for more than 48 hours up to 21 days by continuous rhythm recording and storage, may be considered medically necessary in patients treated for reasons listed in the diagnosis list to monitor for asymptomatic episodes in order to evaluate treatment response. The use of external electrocardiographic event monitors for more than 48 hours up to 21 days that are either patient-activated or auto-activated may be considered medically necessary as a diagnostic alternative to Holter monitoring in patients who experience infrequent symptoms (less frequently than every 48 hours) suggestive of cardiac arrhythmias (i.e., palpitations, dizziness, presyncope, or syncope).

The use of auto-activated external electrocardiographic event recordings may be considered medically necessary in the outpatient setting and are noncovered for inpatient or outpatient observation care.

Long term 30-day monitoring; Telephonic Transmission of ECG involve 24 hour attended monitoring per 30 day period of time; no other EKG monitoring codes can be billed simultaneously with these codes.

https://www.unitedhealthcareonline.com/ccmcontent/ProviderII/UHC/en-US/Main%20Menu/Tools%20&%20Resources/Policies%20and%20Protocols/Medicare%20Advantage%20Policy%20Guidelines/External_Electrocardiographic_Recording.pdf

Government's Case Does not Address Modalities for ECGs

Long-Term ECG Monitoring is defined as a diagnostic procedure, which can provide continuous recording capabilities of ECG activities of the patient's heart while the patient is engaged in daily activities. **These can include continuous, patient-demand or auto-detection devices.** The purpose of these tests is to provide information about rhythm disturbances and waveform abnormalities and to note the frequency of their occurrence.

App. 337

EXHIBIT C

Michael F. Arrigo

marrigo@noworldborders.com +1949-633-5664

Offices in Boston, Pittsburgh, New York, Washington DC, Nashville, Raleigh, Atlanta, Miami Seattle, Salt Lake City, Denver, St. Louis, Chicago, Dallas, San Francisco, Palo Alto, Orange County, San Diego, Honolulu

Education

- **Harvard Law School**, Cambridge MA - Studies in Bio Ethics the study of ethical, legal, technological and social issues in biology and medicine including genetic testing[i]
- **Stanford Medical School, Palo Alto CA -** Studies in Biomedical Informatics and mobile health [ii]
- **University of Southern California, Marshall School of Business, Los Angeles –** Bachelor of Science, Business Administration, 1981; studied in Entrepreneur Program which focuses on the management, marketing and finance of startups, first of its kind U.S.
- **Clinical documentation, medical coding, billing reimbursement, HIPAA transactions, value based care, risk adjustment** (*see* Attachments in this CV).

Professional Affiliations

- Medical Group Management Association (MGMA)
- Health Information Management Systems Society (HIMSS)
- American Academy of Professional Coders (AAPC)
- American Health Information Management Association (AHIMA)
- American Academy of Pain Medicine (AAPM)
- Workgroup for Electronic Data Interchange (WEDI)
- Association for Clinical Documentation Improvement Specialists (ACDIS)
- American Society for Clinical Pathology (ASCP)
- Information Systems Audit and Control Association (ISACA)
- Volunteer, Children's Hospital Medical innovation committee
- Guest lecturer, Contributor, Strategic Financial Management Newsletter, Healthcare Financial Management Association;
- Prior contributor, Healthcare IT News, GovHealth IT, Mobile Health News, Financial Health News

Additional Coursework and Training

- **Villanova University** – Lean Six Sigma and Process improvement 2007
- **Wharton School, University of Pennsylvania –** Leadership Strategies - 1982
- **University of Calif., Irvine –** Computer Science, Statistics, Economics '76 – '78

Legal Experience *(See Separate Document for List of Cases & Opinions)*

1. Retained by **U.S. DOJ** re: Federal investigation into medical data, Health IT / E.H.R. stimulus funds, False Claims Act estimated value of $900 million;
2. Certified as expert by Judge Ambler in hearing re: medical billing, coding and loss / damages calculations
3. Presentations before **FBI**, Department of Justice, and U.S. HHS **Office of Inspector General** involving federal investigation under the False Claims Act.
4. Retained by former RAND Economists and Health IT firm for testimony before **Federal Trade Commission** involving anti-trust, access to clinical data impacting billing & revenue cycle.
5. Retained in five white collar crime cases, alleged fraud valued at over $5 million each
6. Federal, State, written testimony in expert reports, depositions, and court appearances re: **ACA**, **HIPAA**, medical coding and billing, usual customary and reasonable cost of care, Medicaid Expansion, Medicaid waivers for disabled insureds, and ACA Qualified Health Plans, ERISA / Taft-Hartley Trusts, subsidies, rates and actuarial value.
7. Engaged by plaintiffs, class action attorneys, relators, defendants with experience across payors (including Medicare, Medicaid, social security, workers' compensation, private insurance / health plans, ERISA / Taft-Hartley plans), providers (including hospital systems, physician groups, FQHCs, ASCs, IDTFs), patients, healthcare IT, (*see* Attachments for experience in various medical specialties).
8. User of eDiscovery tools such as *Relativity* for document discovery work, structured methods to review large case files with over 50,000 pages in complex litigation.

Industry Awards and Recognition

Arrigo, M. F. 2016 Nominee, Best Legal Blogs of 2016 for healthcare industry sector, No World Borders, Inc.

Publications & Lectures

Arrigo, M. F. (2016) Strategic Financial Management for Healthcare Providers: Clinical Documentation Improvement and Accuracy as a Foundation Value Based Care. Peer review, review by clinical and business executives at Baptist Health, a large academic medical center. Healthcare Financial Management (HFMA). Published August 17, 2016 https://www.hfma.org/sfp/

Arrigo, M. F. (2015) Mobile Health, HIPAA Privacy and Security

Blackberry Sharpens Security with Good Technology Acquisition. Gov. Health IT

http://www.govhealthit.com/blog/commentaryblackberry-sharpens-security-good-technology-acquisition

Arrigo, M. F. (2015) Five Interest-Piquing Trends at HIMSS15. Gov. Health IT
http://www.govhealthit.com/news/5-interest-piquing-trends-himss15

Arrigo, M. F. (2014) Cloud and Mobile Convergence: The Regulatory View. Gov. Health IT
http://www.govhealthit.com/blog/cloud-and-mobile-convergence-regulatory-view

Arrigo, M.F. (2014) HIPAA Plain and Simple / HIPAA for Behavioral Health – Credible Behavioral Health E.H.R. Software Users Conference, Baltimore Maryland (18 March 2014)

Arrigo, M.F. (2014) DSM 5 and ICD-10 – Credible Behavioral Health E.H.R. Software Users Conference, Baltimore Maryland (18 March 2014)

Arrigo, M.F. (2014) Managed Care and Accountable Care for Behavioral Health – Credible Behavioral Health E.H.R. Software Users Conference, Baltimore Maryland (18 March 2014)

Arrigo, M. F. (2011) ICD-10 financial impact vs. mortgage crisis? Gov. Health IT
http://www.govhealthit.com/news/could-icd-10-have-big-financial-impact-mortgage-crisis

Arrigo, M. F. (2012) How a Flaw in the ACO Model Leaves Patients Out. Gov. Health IT
http://www.govhealthit.com/news/how-flaw-aco-model-leaves-patients-out

Arrigo, M. F. (2012) 10 ICD-10 Regulation Myths Demystified. Gov. Health IT
http://www.govhealthit.com/news/10-icd-10-regulations-demystified

Arrigo, M. F. (2012) Real-time location, mobile health gain traction. Gov. Health IT
http://www.govhealthit.com/news/real-time-location-and-mobile-health-solutions-gain-traction-show-roi

Arrigo, M. F. (2013) 3 Top Priorities for CommonWell. Gov. Health IT
http://www.govhealthit.com/news/3-top-priorities-commonwell

Arrigo, M. F. (2013) Commentary: ICD-10 Arrives Early, New Claims Form. Gov. Health IT

http://www.govhealthit.com/news/commentary-icd-10-arrives-early-claims-CMS-coding-HIPAA-icd-9

Arrigo, M. F. (2014) Increased Spending - Big Data, Cloud, mHealth Social. Gov. Health IT
http://www.govhealthit.com/blog/increased-spending-and-savings-tap-big-data-cloud-mhealth-and-social

Arrigo, M. F. (2014) Ebola: How cloud, mHealth, and ICD-10 could help. mHealth News
http://www.mhealthnews.com/blog/ebola-how-cloud-mhealth-and-icd-10-could-help

Arrigo, M. F. (2014) How Cloud and mHealth Ease Claims Processing (also coverage of Prior Authorization / eligibility HIPAA EDI 270/271, referral EDI 278 transaction. Gov. Health IT
http://www.govhealthit.com/news/how-cloud-and-mhealth-promise-ease-claims-processing

Arrigo, M. F. (2014) How to Get Behavioral Health Codes Right. Gov. Health IT
http://www.govhealthit.com/blog/how-get-your-behavioral-health-codes-right

Lectures, Adjunct Faculty, Conference Speaking Engagements

- Arrigo, M. (Speaker) (2015, November 2015) **Medical Device Reimbursement, FDA, FCC and CMS regulatory disruption and opportunities under the Affordable Care Act, ICD-10 and HITECH Act.** BioMed Device and Wireless Device Conference, San Jose California

- Arrigo, M. (Speaker) (2015, September 2015). **Meaningful Use of Electronic Health Records, HIPAA Privacy and Security and potential damages for breaches under the HITECH Act as a foundation for the International Classification of Diseases from the World Health Organization (ICD-10)** – Discussion of risks and opportunities in these two regulations; discrete data, quality measures, medical codes: clinical Documentation, clinical decision support, physician and patient engagement, HIPAA Privacy and Security and revenue cycle. Wolters Kluwer Corporate event presented to audience of over 1,800 participants.

- Arrigo, M. and Nichols J. MD - (Speakers) (2013, November). Claims Data, Clinical Data – Working together to Improve Clinical Documentation for **International Classification of**

Diseases from the World Health Organization (ICD-10). **Workgroup for Electronic Data Interchange (WEDI)** National Conference.

- Arrigo, M. (Speaker) (2012, April 14). **The Perfect Storm in Healthcare - How Disruptive Regulations and Technologies Create Risks and Opportunities** for Medical Coding and Revenue Cycle Management. Affordable Care Act, ICD-10, CORE Operating Rules, and HITECH Act. American Academy of Professional Coders (AAPC) National Conference. Lecture conducted from Las Vegas, NV. http://news.aapc.com/icd-10-monitor-wish-i-were-in-las-vegas/

- Arrigo, M. (Speaker) (2012, June 14). **ICD-10: Impact on Payment Reform**. **Wisconsin Medical Society**. Lecture conducted from Madison, Wisconsin. http://bit.ly/16aclDy

- Arrigo, M. (Speaker) (2013, April 23). **The Perfect Storm in Healthcare** - How Disruptive Regulations and Technologies Create Risks and Opportunities for Medical Coding and Revenue Cycle Management. Affordable Care Act, ICD-10, CORE Operating Rules, and HITECH Act. **Scripps Healthcare Summit 2013. Lecture conducted from La Jolla, San Diego California**.

- Arrigo, M. (Speaker) (2012, May). How **ICD-10 and Payment Reform Will Change the Radiology Revenue Cycle**. **Radiology Business Management Association (RBMA), Orlando Florida.**

- Arrigo, M. (Speaker) (1994 - 1995). **Impact of the Internet on medical and financial businesses**, **Loyola University, Los Angeles CA**

- Arrigo, M. (Speaker) (1994 - 1995). **Impact of the Internet on medical and financial businesses**, **University of California, Irvine CA**

2010 to present **Instructor, HIPAA Privacy and Security, HITECH Act Electronic Health Records, value based care, medical coding and billing audits, Affordable Care Act,** Best practices in HIPAA and HITECH Act Information Privacy and Security[1] and Meaningful Use, Best practices Health IT, process improvement, eligibility and coverage determinations for value based care[2] Recent courses included instruction at these venues:

- American Health Information Management Association 2016, Baltimore, MD
- JP Morgan Healthcare Conference 2015, San Francisco, CA
- Wolters Kluwer 2015 webcast

[1] Trained by published author in HIPAA privacy and security and advisor to CMS, HHS on Meaningful use of Electronic Health Records, currently lead training sessions for HIPAA covered entities
[2] Lead training for pharmacists, hospitals, physicians, health IT value based care firms

not for publication in any form other than litigation consulting with permission when retained

- Duke Life Health System 2013, Pittsburgh, PA
- HIMSS 2014
- AAPC Annual Conference 2012, Las Vegas

Non- Litigation Consulting in Healthcare, Software, Financial Services

2007 to Present **- No World Borders** – I lead a healthcare data, regulatory, and economic consulting firm as Managing Partner**.** Our business provides advisory services on disruptive health care regulations for hospitals, insurance companies, self-insured employers, and health IT companies and investors.

Summary of Accomplishments and Experience

I work with hospital systems, physician groups, and health IT companies, health plans, investors, and law firms. I was selected as an expert for a landmark Federal Trade Commission case regarding healthcare data, regulations and economics. I currently serve as managing partner of No World Borders. I am:

- A writer and speaker quoted in Wall Street Journal, and a regular speaker with published works as an expert in the field.
- Prepared by leading litigation firm in Rule 702 including applying scientific or specialized knowledge Federal rules (702(a)); facts (702(b)); application of principles and methods (702(c)); application of criteria, principles, methodology, test methods (amended in *Daubert*, 2000 - (702(d)) before FTC Commissioner.
- An advisor to value based care companies including Medicare Advantage, Medicare Shared Savings Accountable Care Organizations.
- Led investor diligence on over $7 billion in health care merger and acquisition transactions.
- Trained in clinician, coder, medical billing, claims, E.H.R, hospital and practice management software, regulatory, usual, customary and reasonable (UCR) medical and prescription charges. Application of Inpatient Prospective Payment System (IPPS), Outpatient Prospective Payment System (OPPS), Medicare Physician Fee Schedules (MPFS) Part A, Part B, Physician Fee Schedules, U.S. standard wage indices, geographic adjustment factors (GAFs), market charges comparisons, where no collateral source rule is at issue, market reimbursement by health, auto, liability payors.

- Opinions on over $2 billion in medical reimbursements for inpatient facilities (inpatient prospective payment system or IPPS and DRGs, ICD-9) and ambulatory (non-facility using CPT codes)

Regulatory Consulting for Health Care Provider and Healthcare I.T. Firms

I competed for, won and led these among other account engagements where large global firms were also bidding on the business:

- **Duke Life Point Academic Medical Ctr Pittsburgh -** *ACO, ICD-10, Revenue Cycle Strategy; HCC risk adjustment for Medicare Advantage. Evaluate over $1 billion in health care claims for risk adjustment, audit quality using RADV methods, clinical documentation coding quality. Evaluate Meaningful Use compliance risk with respect to storage and security of discrete data from medical records, data conversion strategies, analytics strategies.*
- **Advisory to E.H.R., Accountable Care Organizations, practice management IT companies -** *manage a team that has advised over 100 companies on Meaningful Use, Medicare Advantage, ACA, ICD-10 regulations. Ambulatory, acute care – MU1, MU2, DSM-5, CPT, ICD-9, ICD-10, clinical documentation, HIPAA, Clinical Quality Measures, CA Civil Code §56;*
- **Nemours Children's Hospital, Orlando Florida** *Meaningful Use of Electronic Health Records, HIPAA transactions for claims processing, HIPAA secure clinical and physical plant data interoperability strategy of clinical and health care claims data using enterprise web services solutions. Sharing of data in emergencies between clinical staff and security to protect pediatric patients.*
- **Credible, Inc. a leading behavioral health electronic health record software vendor** Advise regarding compliance with HIPAA Privacy and Security in general and specific privacy and security rules for the Behavioral Health specialty, International Classification of Diseases version 10 versus Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM 5), Accountable Care Organizations and Managed Care for Behavioral Health.

Regulatory Consulting for Health Plan, Self-Insured Employer Regulations

I competed for, won and led these among other account engagements where large global firms were also bidding on the business:

- **Excellus Blue Cross Blue Shield** – Rochester New York. Lead consulting engagement to remediate health plan enrollment process and TriZetto Facets Claims system. Rescue project from off-budget, off plan and restore to on time on budget.

- **Blue Cross Blue Shield / Triple – S** (Salud Puerto Rico) – Lead implementation of TriZetto QNXT claims system including all process models, software implementation and project management office.

- **Preferred Care – Florida -** Medicare Advantage HEDIS 5-Star Ratings, provider network clinical data, Utilization Management, Coordination of Benefits, Case Management and claims processing, chart review quality audits and analytics, risk adjustment using HCC and ICD-9 coding, RADV audit methods, RAPS file analytics.

- **United Healthcare, Florida -** Medicare Advantage HEDIS 5-Star Ratings, provider network clinical data, Utilization Management, Coordination of Benefits, Case Management and claims processing using HCC and ICD-9 coding, RADV audit methods, RAPS file analytics.

- **Public Employees Health Plan – Salt Lake City Utah –** Advise and assess re: new medical coding and medical policy management remediation to comply with ICD-10 which impacts medical policy plan design, actuarial processes, covered amounts, utilization management, eligibility, referrals, covered amount and other factors.

- **Regence BlueCross BlueShield, Seattle, Salt Lake, Portland** - HITECH Act, HIPAA 5010, ICD-10 processes, DRGs, Ambulatory claims, Ancillary Services, and IT architecture to enable these capabilities which impacts medical policy plan design, actuarial processes, covered amounts, utilization management, eligibility, referrals, covered amount calculations and other factors.

- **Walmart – largest self-insured non-military employer globally –** advice regarding ERISA Plans, Taft-Hartley Trusts, Minimum Essential Coverage, HIPAA insurance claims transactions, CORE operating rules, ICD-10, Affordable Care act business and regulatory issues and underlying systems and process issues for the largest self-insured employer in the world.

- **TennCare – Tennessee Medicaid and TN Insurance Exchange eligibility**

- ***Citra Health Solutions, Jacksonville FL*** *– Advisor to CEO. Advise leadership regarding value based care, HIPAA privacy and security, meaningful use, strategic partnerships and acquisitions for Medicare Advantage and Accountable Care market. Focus on Value Based Pricing, Medicare Advantage Risk Adjustment using HCCs; population health, patient and physician engagement and quality reporting.*

Investor Diligence - $4 billion in Health IT M&A transactions

Selected as advisor, investor diligence on large healthcare mergers and acquisitions.

- **London PE Firm -** pre-IPO cloud security business for healthcare.
- **Kleiner Perkins Caufield & Byers**, Silicon Valley **–** work with founding partners of VC that funded Google, Netscape, Amazon, Amgen, Intel, Sun Microsystems on largest cloud healthcare investment *in Medicare Advantage and Accountable Care population health management and analytics*
- In-Network and Out of Network medical charges, **340B Drug discount provider**

- **NY PE Firm** – diligence on $500 million acquisition of Medicare Administrative Contractor (MAC) electronic data connectivity and services company. Evaluate financial projections and growth potential, capabilities regarding claims status, new EDI standards, medical policy plan design, actuarial processes, covered amounts, utilization management, eligibility, referrals, covered amount calculations and other factors.

Medical Device, Pharmaceutical Regulatory Compliance

Abbott Labs, Medical Optics Div. (formerly Advanced Medical Optics) - Regulatory Affairs, FDA Compliance – led global complaint handling roll out (US, UK, EU, Asia) of pharmacovigilance solution supporting FDA Adverse event reporting rules, National Drug Codes (NDCs), HCPCS, formularies, and health insurance coverage determinations for pharmaceuticals. Consulted to Optics division on global FDA Adverse Event reporting system, pharmacovigilance system for medical devices and pharmaceuticals.

Led hardware and software development team through IQ/OQ/PQ process (IQ stands for Installation Qualification. OQ is Operational Qualification and PQ is Performance Qualification. Before you even get to IQ, OQ, PQ, if you're acquiring a new piece of equipment, you'll need design specifications that define exactly what's in that piece of equipment) for FDA approval for medical device.

Prior Experience

October 2002 to February 2007 – **First American** / **CoreLogic - SVP eCommerce –** *Banking solutions $8 billion firm. Led one of the largest most complex Sarbanes Oxley IT audits in the U.S. according to attorneys and accounting firm. Led roll out of single platform eCommerce solution to integrate Wells Fargo, JP Morgan Chase, Bank of America and other transactions for mortgage loan origination (credit, valuation, tax, flood, title, etc.), closing, securitization.*

2002 to October 2003 – Fidelity - SVP eCommerce – *Banking solutions $12 billion firm*

May 2000 to 2002 – Citrix Systems – President & CEO (Erogo, a SaaS Cloud medical and internet billing company) Built *cloud SaaS internet and medical billing company from $500k to $10 million in revenue and investment by Citrix*

June 1997 to October 1999 to 2000 *Axway / Worldtalk,* Silicon Valley – VP Marketing for a secure email and Cloud / Internet of Things (IoT) rules based interoperability company.

June 1997 to October 1999 - **Heidrick & Struggles,** Silicon Valley – President & CEO**, LeadersOnline** – Hired by premier executive search firm to *build and lead an online recruiting business to diversify and assist with IPO. Set strategy acquired assets led launch of*

Internet recruiting business as portion of IPO prospectus (S-1) and road show with Goldman Sachs, adding $100 million to market cap of Heidrick at IPO.

September 1981 – May 1997 – Smith Tool, **Oracle, HP, Symantec, Intel, ParcPlace Systems, Borland, Ashton-Tate** – Silicon Valley, Southern California, Boston – roles from analyst to Product Manager, VP Marketing and Sales, Corporate Development. Built a company from $2 million to $50 million buyout, owner of $350 million P&L and brand re-launch, turn around.

CV ATTACHMENT 1
Healthcare Transactions and Processes
to Support Claims, Care Coordination and Financial Value of Care

Health Care Processes – Health Plans

- **Value Based Care Reporting** for **Medicare Part C** and **Medicare Shared Savings Plan Accountable Care Organizations** including: HEDIS, MSSP 33 measures, HCC coding, risk adjustment, risk corridors, RADV and RAC audits, compliance platforms
- **Payor - provider contracting** – Mr. Arrigo leads a team that has over **30 years of health care provider and health insurance contract negotiation experience for hospitals, clinics and diagnostic services providers.** Mr. Arrigo and his team have advised 18 hospitals and clinics, four medical device and pharmaceutical firms, two healthcare IT firms, and two four insurance firms as well as CMS in all 50 states on new regulatory impacts. He and his team have advised on over 2,000 contracts.
- **Explanation of benefits** – Mr. Arrigo's team advises health plans on the revisions in EOBs that must be made to comply with new laws and regulations such as ICD-10.
- **Actuarial & Underwriting** – Mr. Arrigo and his team advise health plans on shifts in coverage determinations and medical policy based on the Affordable Care Act, ICD-10, CORE Operating rules and other regulations.
- **Coverage determination** planning and policy, IT systems supporting new regulations.
- **Claims processing metrics** – pass through rates, manual vs. electronic claims adjudication and **Utilization Management (UM) rates**.
- Payor - provider contracting – Mr. Arrigo leads a team that has over **30 years of health care provider and health insurance contract negotiation experience for hospitals, clinics and diagnostic services providers.** Mr. Arrigo and his team have advised 18 hospitals and clinics, four medical device and pharmaceutical firms, two healthcare IT firms, and two four insurance firms as well as CMS in all 50 states on new regulatory impacts. Over time he and his team have advised on over 2,000 contracts.

Health Care Processes and IT – Hospitals, Clinics Physicians and Other Providers

- Readmissions metrics
- Clinical documentation, coding, claims reimbursement
- Admission and discharge processes and metrics
- Revenue cycle management and metrics (DNFB – discharged not final billed, etc.)

CV ATTACHMENT 2

Private Payor, ACO, IDN, Medicare (Part A, B, C, D), Health IT Experience

Additional Experience with Health Systems Providers
ICD-10, HIPAA 5010, HIPAA Privacy and Security, Clinical Quality Measures Consulting Expert Work

Feather River Hospital -
http://www.frhosp.org

Frank R. Howard Memorial Hospital -
http://www.howardhospital.com

Glendale Adventist Medical Center -
http://www.glendaleadventist.com

Loma Linda University and Loma Linda Medical Center -
http://www.llu.edu/llumc/

San Joaquin Community Hospital -
http://www.sjch.us

Selma Community Hospital -
http://www.adventisthealthcv.com

Sonora Community Hospital -
http://www.sonoramedicalcenter.org

St. Helena Hospital -
http://www.sthelenahospital.org

Ukiah Valley Medical Center -
http://www.uvmc.org

White Memorial Medical Center -
http://www.whitememorial.com

Additional Experience with Health Plans

ICD-10, HIPAA 5010, HIPAA Privacy and Security, Clinical Quality Measures Consulting Expert Work

- Blue Cross Blue Shield of Oregon
- Blue Cross Blue Shield of Utah
- Public Employees Health Plan of Utah
- Blue Cross Blue Shield of Idaho
- Blue Cross Blue Shield of Washington State
- CareFirst Blue Cross – Mid-Atlantic Region
- BCBS of Tennessee – Chattanooga, TN

Over ten **Value Based Care Organizations** (**Accountable Care Organizations or ACOs** and **Medicare Advantage / Part C** Plans including Essence Health Plan St. Louis, United Healthcare and Preferred Care Partners.

CV ATTACHMENT 3

Investor Transactions and Diligence

Investor	Target Company	Enterprise Value ($millions)
Confidential PE fund	Provided opinions re coding for diagnostic medical devices and their FDA approval process relating to Independent Diagnostic Testing Facility (IDTF). Opinion re: Fair Market Value (FMV) of medical directors; risk assessment of professional component (PC) and technical component (TC) for EEG and EKGs	Over $500 million
Confidential PE fund	Advise regarding Medicare Secondary Payor health care data, regulations, valuation structure for inpatient and outpatient medical claims	$2.0 billion +
Confidential $4 billion PE fund, New York	Ability Networks (leading Medicare claims technology infrastructure)	$550
Confidential $4 billion PE fund, New York	Health Port, an electronic release of HIPAA information service provider	$120
PE fund, confidential, west coast	Confidential ePCR (electronic patient care record) EMS (emergency management system) platform	Confidential
$300 million specialty PE fund, New York	Orange Health (now Citra Health) (Value based care for ACOs, MA plans)	$25
$300 million specialty PE fund, New York	MZI, a health care claims processing software vendor	$25
Kleiner Perkins Caufield & Byers, Menlo Park CA	Lumeris, an Essence Global Holdings Co. (Value based care for ACOs, MA plans)	$600
Large Private Equity firm, London	Covisint, a spin out of Compuware (cloud user access mgmt.)	$450
U.S. Private Equity firm, San Francisco	Evaluation of Diabetic population insulin initiation and titration mobile technology for glycemic control compared with standard clinical practices.	TBD
U.S. Private Equity firm	Drug formulary business, impact of specialty reimbursement in endocrinology, hematology and dermatology and new drug discoveries	Confidential

Public Debt Investor	Top 10 E.H.R. software co. debt offering	confidential
Confidential	Confidential healthcare analytics co.	$280
Confidential	Confidential hospital revenue cycle management (RCM) business	$190
Confidential	Confidential Electronic Data Interchange claims co. health insurance	$150
Confidential	Genetic Testing and Precision Medicine	$300
Confidential	Health system with multi-site hospital, physician group, clinic diagnostic imaging	$1,000
Confidential	Health IT solutions: Drug Dispensary automation for oral and Intravenous Anti-Emetic Drugs for Chemotherapy Chemotherapeutic Regimen	confidential
Confidential	Pharmacy Benefit Management (PBM) business	$600
Confidential	Independent Diagnostic Testing Facility (IDTF) that provides EEG and EKG services	$250
	Total Enterprise Value ($millions)	**$7.7 Billion**

CV ATTACHMENT 4 (page 1 of 2)

Affordable Care Act, Medicaid, Social Security, Insurance Exchange, Benefits Determination and Orthotics Reimbursement

Experience with regulations, technology and requirements for systems supporting 15 State HHS Medicaid insurance Exchange eligibility systems including these business requirements, which in turn provide state-by-state eligibility for Affordable Care Act insurance mandates:

Types of Exchanges and Enrollee Characteristics:

- Federal (HHS) Exchanges "Federally-Facilitated Marketplace" ("FFM") which are being used in states such (FL, GA, NC, SC, VA, AL, MS, MO, AR, LA, OH, PA, IL, OK, MT, UT, ND, SD, NE) and provider contracting
- State Based Exchange ("SBEs") and state-by-state variances (CA, WA, ID, CO, KY, MN, NY, VT, RI, CT, MA, DE, MD, DC)
- State MMIS – Medicaid Management Information Systems, which provide some of the eligibility technology platform for the Exchanges

Eligibility Process, Technology for State Health and Public Welfare

- Request for insurance, pre-existing conditions under Affordable Care Act
- **42 CFR MAGI** – Modified Adjusted Gross Income (U.S. Citizenship, criminal and State Residency, household size and FPL % [see FPL])
- FPL percentage – percent of Federal Poverty Level
- TANF – Temporary Assistance to Needy Families (formerly AFDC) / The Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (Public Law 104-193) and **TEFRA**
- SNAP – Supplemental Nutrition Assistance Program (formerly food stamps)
- Medicaid – free and low-cost health care to low income families
- CHIP – Children's Health Insurance Program (Medicaid for kids)
- Women, Infants & Children (WIC) – nutritional supplement for pregnant women, infants and children (until school age)
- Section **1619(b) of the Social Security Act** re: Social Security beneficiaries, Medicaid eligibility.

Durable Medical Equipment, Prosthetics, Orthotics, Supplies (DMEPOS)

Generally familiar with 280 classifications of HCPS and specifically:

1. Alarm Device
2. Ambulatory Traction Device
3. CPAP Device
4. Dynamic Flexion Devices
5. EMG Device
6. Foot Off Loading Device
7. Monitoring Feature/Device
8. Ocular Prosthetics
9. Oral Device to Reduce Airway Collapsibility
10. Orthopedic Devices
11. Pain Management
12. Passive Motion Exercise Device
13. Power Mobility Devices
14. Reaching/Grabbing Device
15. Repair of Prosthetic Device
16. Repair/Modification of Augmentative Communicative System or Device
17. Skin Piercing Device
18. Speech Generating Device
19. Standing Devices/Lifts
20. Stimulation Devices
21. TMJ Device and Supplies
22. Ventricular Assist Devices

CV ATTACHMENT 4 (page 2 of 2)

State HHS Eligibility Systems and Jurisdictions

Jurisdiction	State Systems and Processes
Alaska	Eligibility Information System (EI)
Arizona	Arizona Technical Eligibility Computer System (AZTECS)
Georgia	SHINES, COMPASS, Vitale Events, Medicaid Data Broker
Hawaii	Hawaii Automated Welfare Information System (HAWI)
Kansas	Kansas Automated Eligibility & Child Support Enforcement System (KAECSES)
Louisiana	Medicaid Eligibility Data System (LA MEDS)
Massachusetts	Mass 21st Century Disability Policy (MA-21)
Minnesota	MAXIS – state, county eligibility for public assistance, health care; exchanges data with Medicaid Management Information System (MMIS), MN Employment and Economic Development, MN Dept. of Finance, and US Social Security Admin
Mississippi	Mississippi Applications Verification Eligibility Reporting Information and Control System (MAVERICS)
Pennsylvania	COMPASS – health care, cash, long-term, home, supplemental nutrition (SNAP) eligibility
Rhode Island	INRhodes and UHIP data and functions for the Family Independence Program, Food Stamps, Child Support Enforcement, Medicaid Eligibility, Child Care, Public Assistance
South Carolina	Family Independence Financial System (FIFN)
Tennessee	TennCare and **SSI** (Supplemental Security Income Under Social Security Administration)
Vermont	ACCESS
Washington DC	Automated Client Eligibility Determination System (ACEDS)
Wyoming	EPICS (Eligibility Payment Information Computer System)

CV ATTACHMENT 5

Meaningful Use of Electronic Health Records

Mr. Arrigo manages a team that has worked with over 50 electronic medical records vendors and health care providers regarding achieving software certification for Meaningful Use (MU) under the HITECH Act as well as MU implementations, attestations, and audit defense v. CMS, OIG and CMS Auditors

Six of the Top 10 Electronic Health Record Companies – Athenahealth, Cerner, Epic, McKesson, NextGen; assessed five mid-tier E.H.R. companies with respect to Meaningful Use, HIPAA and Information Safeguards compliance.

Meaningful Use (**MU**) is composed of a complex list of Objectives, including HIPAA privacy, Personal Health Information Safeguards, Clinical Quality Measures (**CQMs**), clinical decision support (**CDS**), transitions of care, data portability, auditable events, patient engagement, and other measures. Mr. Arrigo has opined as an Expert regarding MU provides opinions and guidance on all of the following factors:

- Authorized Testing and Certifications Bodies (ATCBs) and processes
- Eligible Hospital (EP) and Eligible Provider (EP) attestations and audit defense under Medicare and Medicaid in Civil and Criminal defense cases.
- Data quality check on numerators and denominators in live data vs. attestation reporting.
- Stimulus funds, OIG, CMS auditors
- HHS OCR, HIPAA breaches, State CMIA breaches and stimulus eligibility
- Modular and Complete E.H.R. certifications
- Discrete data structures
- HIPAA Privacy and Security Assessments as a Component of MU and the Administrative, Physical, Technical Safeguards of HITECH Act as well as Operational Policies, Procedures and Documentation and HIPAA overlapping requirements.
- Clinical workflow for both acute care and ambulatory E.H.R.s
- Rollout Phase I, II of E.H.R. implementation in Emergency and Radiology departments
- Medication dispensing modules
- Standardized the implementation process and used as quality control while contracted to U.S. HHS / ONC to educate Regional Extension Centers providing national education and quality standards that were adopted by ONC.

- Standardized at the highest benchmarking level so that every implementation met the same criteria.

Team Qualifications

- Served as co-chair of Critical Access Hospital boot camp for U.S. HHS for hospital E.H.R. implementations across the country
- Experience training the implementation process for RECs, co-chaired the committee that built the curriculum for a proper curriculum
- Served as E.H.R. advisors for the American Society of Oncologists, and American Gastro Institute standardized institute
- E.H.R. contract negotiation process Value Added Reseller (VAR) selection
- Hospital, Critical Access Hospital, Federally Qualified Health Centers, and Community Hospital (Medicare and Medicaid stimulus)
- Published authors in Meaningful Use and HIPAA
- Advised U.S. Department of Justice regarding E.H.R., §495.6 Meaningful use objectives and measures for EPs (physicians), eligible hospitals, and Critical Access Hospitals.
- Attestation processes including compliance with
    a. computerized provider order entry (CPOE) for medication orders
    b. drug-drug and drug-allergy interaction checks, and “The EP, EH, or CAH has enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.”
    c. maintain an up-to- date problem list of current and active diagnoses
    d. Generate and transmit permissible prescriptions electronically (eRx) and access to external formularies
    e. medication information as structured data
    f. maintain Active Medication allergy list
    g. patient demographics, vital signs, smoking status, quality measures, patient education, clinical decision support, syndromic surveillance, immunization records, and transitions of care
    h. Patient access to records via web or mobile portal

Meaningful Use Stage 1:

Eligible professionals:

- 13 required core objectives
- 5 menu objectives from a list of 9
- Total of 18 objectives

Eligible hospitals and CAHs:

- 11 required core objectives
- 5 menu objectives from a list of 10
- Total of 16 objectives

Meaningful Use Stage 2:

Eligible professionals:

- 17 core objectives
- 3 menu objectives that they select from a total list of 6
- Total of 20 objectives

Eligible hospitals and CAHs:

- 16 core objectives
- 3 menu objectives that they select from a total list of 6
- Total of 19 objective

CV ATTACHMENT 6

Healthcare Business Transactions, Supporting HIPAA X12 Electronic Transactions

45 CFR Part 162 Health Insurance Reform; Modifications to the Health Insurance Portability and Accountability Act (HIPAA); Final Rules

1. Health Care Eligibility Benefit Inquiry and Response – EDI 270/271
2. Health Care Claim Status Request / Response – EDI 276/277
3. Health Care Services Request for Review / Response (Prior Auth.) – EDI 278
4. Payroll deductions for premiums – EDI 820
5. Benefit enrollment and maintenance – EDI 834
6. Health care claim: Payment / Advice – EDI 835,
7. Health Care Claim: institutional, professional / dental –
    a. EDI 837, Pharmacy claim (NCPDP),
    b. Coordination of Benefits (COB) and third-party liability
    c. Fraud waste and abuse analytics and Special Investigative Unit (SIU)

Modifications to § 162.1102, § 162.1202, § 162.1302, § 162.1402, § 162.1502, § 162.1602, § 162.1702, and § 162.1802 to adopt the ASC X12 Technical Reports Type 3 (TR3), Version 005010 (Version 5010) reporting of clinical data, enabling the reporting of ICD–10–CM diagnosis codes and ICD–10–PCS procedure codes

CV ATTACHMENT 7

Revenue Cycle Management, Clinical Documentation and Coding Processes

Lead team that implements hospital system assessments for ICD-10 and CPT coding compliance and quality, including:

CDI (Clinical Documentation Improvement) strategy and alignment between HIM department, coders, nursing, physicians. Benefits of coder-physician collaboration, and securing results in improved coding. Engage case managers to focus on CDI trends, work with physicians that are the largest admitters. Understanding of key processes including:

Patient intake
Patient assessment
Documentation of care
Insurance coverage determination
Discharge activities
Provider communications
Referrals
Prior authorizations
Coding
Charge capture, super bills
Billing
Revenue collection
Vendor impacts
EHR and other system readiness to support clinical documentation improvement
IT plans
Impact on concurrent initiatives
Reporting
Quality improvement efforts
Payor readiness and processes; medical policy assumptions for contracting
Institutional Review Board (IRB) impact review for ICD-10
Data warehouse and business intelligence “retooling” of analytics required.
National Correct Coding Initiative (NCCI), Modifiers, Bundling and Unbundling Criteria According to Centers for Medicare and Medicaid

CV ATTACHMENT 8 – Drug Pricing Practices

Experience using analytics to identify UCR (Fair Market Value) in Pharmaceutical Pricing

- Re-Defining AWP
- % Factor
- NDC price reporting
- Mark-Ups & Price Spreads
- Backroom Processor Schemes
- Rebate Schemes
- Flat, Access, Market Share
- Rebate Disguising
- Rebate Pumping
- Re-Defining “Brand” and “Generic”
- Formulary Steering
- Pre-Authorization Schemes
- Clinical Rules & Protocols
- Mail-Order Schemes
- Leveraging Captive Facility
- Multiple MAC Lists
- Drug Switching
- Drug Repackaging
- Fraudulent Plan Design
- Zero Cost Scripts
- Higher Than Logic
- Pocketing Refunds, Reversals and Returns
- Payor Account Crediting Tricks
- Specialty Drug Issue

CV ATTACHMENT 9

HIPAA Privacy Rule and HIPAA Security Rule, HITECH Act Information Safeguards and State Statutes in WA, CA, NV, NY, MA, FL

Lead team that assesses and advises regarding industry best practices and implementation of HIPAA Privacy and Security as well as HITECH Act, including:

Security best practices for HIPAA Covered Entities

HHS Security Standards:

1. **Administrative** Safeguards
2. **Physical** Safeguards
3. **Technical** Safeguards
4. **Organizational Policies and Procedures** and Documentation Requirements

Opinions regarding but not limited to:

- "Breach" under the Privacy Rule, including but not limited to, 45 C.F.R. § 164.402.
- "Business Associate" under the Privacy Rule, including but not limited to, 45 C.F.R. § 160.103.
- "Covered Entity" under the Privacy Rule, including but not limited to, 45 C.F.R. § 160.103.
- "Designated Record Set" under the Privacy Rule, including but not limited to, 45 C.F.R. § 164.501.
- "Disclosure" under the Privacy Rule, including but not limited to, 45 C.F.R. § 160.103.
- "Electronic Protected Health Information" or "ePHI" under the Privacy Rule, including but not limited to, 45 C.F.R. § 160.103.
- "Individual" under the Privacy Rule, including but not limited to, 45 C.F.R. § 160.103.
- "Minimum Necessary" under the Privacy Rule, including but not limited to, 45 C.F.R. §§ 164.502(b) and 164.514(d).
- "Privacy Rule" Standards for Privacy of Individually Identifiable Health Information at 45 C.F.R. Part 160 and Part 164, Subparts A and E.
- "Protected Health Information" or "PHI" in 45 C.F.R. §§ 160.103 and 164.501, and is the information created or received by BA
- "Required by Law" in 45 C.F.R. § 164.103.
- "Security Incident" shall have the meaning given to such term under the Security Rule, including but not limited to, 45 C.F.R. § 164.304.
- "Security Rule" 45 C.F.R. Part 160 and Part 164, Subparts A and C.

not for publication in any form other than litigation consulting with permission when retained

- "Subcontractor" under the Privacy Rule, including but not limited to, 45 C.F.R. § 160.103.
- "Unsecured Protected Health Information or PHI" under the Privacy Rule, including but not limited to, 45 C.F.R. § 164.402.
- "Use" under the Privacy Rule, including but not limited to, 45 C.F.R. § 160.103.

CV ATTACHMENT 10 Rural Health Centers (RHCs), Critical Access Hospitals (CAHs), Federally Qualified Health Centers (FQHCs)

Section 10501(i)(3)(B) of the Affordable Care Act

Rural Health Clinics Act (P.L. 95-210)

- Use of grants under TRICARE program under chapter 55 of title 10, United States Code for administrative programs.
- All-Inclusive Rate Reimbursement (**AIRR**)
- Prospective Payment System (**PPS**)
- CMS 222 financial reports for RHCs and FQHCs and basis for reports supported by clinical documentation and medical coding
- Baseline Practitioner Productivity Standards
- Historical perspective regarding Benefits Improvement and Protection Act of 2000 (BIPA) and State Medicaid program reimbursement RHCs (In lieu of cost-based reimbursement, Medicaid shifted RHCs to a PPS methodology)
- Industry best practices and guidelines and compliance to U.S. HHS / Health Resources and Services (HRSA) standards including:

		STATUTE
1.	Needs Assessment	Section 330(k)(2) of the PHS Act Section 330(k)(3)(J) of the PHS Act
2.	Required and Additional Services	(Section 330(a) of the PHS Act) (Section 330(h)(2) of the PHS Act)
3.	Staffing Requirement	(Section 330(a)(1), (b)(1)-(2), (k)(3)(C), and (k)(3)(I) of the PHS Act)
4.	Accessible Hours of Operation/Locations	(Section 330(k)(3)(A) of the PHS Act)
5.	After Hours Coverage	(Section 330(k)(3)(A) of the PHS Act and 42 CFR Part 51c.102(h)(4))
6.	Hospital Admitting Privileges and Continuum of Care	(Section 330(k)(3)(L) of the PHS Act)
7.	Sliding Fee Discounts	(Section 330(k)(3)(G) of the PHS Act, 42 CFR Part 51c.303(f)), and 42 CFR Part 51c.303(u))
8.	Quality Improvement/Assurance Plan	(Section 330(k)(3)(C) of the PHS Act, 45 CFR Part 74.25 (c)(2), (3) and 42 CFR Part 51c.303(c)(1-2))

9.	Key Management Staff	(Section 330(k)(3)(I) of the PHS Act, 42 CFR Part 51c.303(p) and 45 CFR Part 74.25(c)(2),(3))
10.	Contractual/Affiliation Agreements	(Section 330(k)(3)(I)(ii), 42 CFR Part 51c.303(n), (t)), Section 1861(aa)(4) and Section 1905(l)(2)(B) of the Social Security Act, and 45 CFR Part 74.1(a) (2))
11.	Collaborative Relationships	(Section 330(k)(3)(B) of the PHS Act and 42 CFR Part 51c.303(n))
12.	Financial Management and Control Policies	Section 330(k)(3)(D), Section 330(q) of the PHS Act and 45 CFR Parts 74.14, 74.21 and 74.26)
13.	Billing and Collections	(Section 330(k)(3)(F) and (G) of the PHS Act)
14.	Budget	(Section 330(k)(3)(D), Section 330(k)(3)(I)(i), and 45 CFR Part 74.25)
15.	Program Data Reporting Systems	(Section 330(k)(3)(I)(ii) of the PHS Act)
16.	Scope of Project	(45 CFR Part 74.25)
17.	Board Authority	(Section 330(k)(3)(H) of the PHS Act and 42 CFR Part 51c.304)
18.	Board Composition	subsection (g), (h), (i), or (p). (Section 330(k)(3)(H) of the PHS Act and 42 CFR Part 51c.304)
19.	Conflict of Interest Policy	(45 CFR Part 74.42 and 42 CFR Part 51c.304(b)).

CV ATTACHMENT 11 - Clinical Documentation, Coding, Billing, Reimbursement Training

1. National Correct Coding (NCCI) claims edits, Sept 2012.
2. Ambulance billing fees and trauma triage and State, Federal CDC trauma activation criteria Sept 2012.
3. Behavioral health, November 2013[iii]
4. Cardiology, November 2013
5. Family practice and internal medicine, November 2013
6. Obstetrics, November 2013
7. Oncology, November 2013
8. Urology, November 2013
9. Orthopedics, November 2013
10. General Surgery, and Dental, November 2013
11. Plastic Surgery, November 2013
12. HCC, risk adjustment, November 2013[iv]
13. DRG calculations, ICD-10, IPPS, OPPS payment systems November 2013[v]
14. Diagnostic Imaging & Nuclear Medicine (PET-Scans) September 2014[vi]
15. Medical Auditing, including focus on anesthesiology, pathology, evaluation management, radiology, chemotherapy, psychotherapy, physical therapy, modifiers, medical necessity. November 2015[vii]
16. Dermatopathology diagnosis relevant to medical specialty, 2016
17. Dietetics and Nephrology, insulin DME billing for diabetes, December 2015, AHIMA
18. Liens, balance billing, subrogation seminar, 2014
19. Affordable Care Act 'metal' plans, Medicaid expansion, Federal Poverty Level guidelines on cost of care, 2014
20. Coding and reimbursement for Pain Management, December 2015; Outpatient physical, occupational, and speech therapy, ambulance and non-emergency transportation, January 2016[viii]
21. Valuing episodes of Care: a) episodic, b) bundled payments, c) value based payment / risk adjustments, d) episode groupers, methodologies, e) PBM / pharmacy charges, f) costs associated with complications, g) prospective, retrospective, and predictive modeling; h) claims adjudication in episodic processes, ACOs, MAOs, fiscal intermediaries, PROMETHIUS analytics payment model for risk adjustment, comorbid factors and cohorts, data required to produce episodic care analysis; June 2016[ix]

CV ATTACHMENT 12 – Medical / Laboratory Test Fees

Opinions regarding economic value and medical necessity (based on the diagnosis of a licensed medical professional or retained medical expert provided to me as a precursor to rendering my opinion) as determined in payor medical policies and coverage determinations for medical laboratory test that can be used to detect, diagnose, or monitor diseases, disease processes, and susceptibility to disease or predisposition based on genetics. Areas of expertise include:

1. diagnosis (associated diagnosis codes are an important indicator of medical necessity as determined in payor medical policies and coverage determinations) and billing codes including:
    a. ICD-10-CM which is U.S. standard from October 1, 2015 forward
    b. ICD-9-CM – for dates of service prior to October 1, 2015
    c. CPT – for outpatient procedures (for example 8500 - Blood count; blood smear, microscopic examination with manual differential WBC count)
    d. NCCI – National Correct Coding Initiative to verify whether bundled procedures and other factors are acceptable
2. overview of the test
3. utility - when/why/how the test is used
4. diseases the test is often used to detect or monitor as this pertains to coding and billing and economic value of the test in a specific geographic market or based on national standards, as well as:
    a. specimen collection methods/procedures (for example, whole blood collection)
    b. testing methodology (for example, hematology)
    c. usual turnaround time (for example, days elapsed time)
    d. reference ranges for test results (normal, abnormal, male / female values etc.)
    e. additional or related tests

NOTE: Interpretation of tests is performed by a licensed medical professional and if that interpretation is provided to me in patient medical record(s), it may be useful in opinions regarding payer determinations or economic value. I do not give medical opinions.

CV ATTACHMENT 13 – Ambulance, Trauma Activation Fees, Anesthesiology

Industry best practices and guidelines for determining economic value and medical necessity (which may be based on the diagnosis of a licensed medical professional or retained medical expert provided to me as a precursor to rendering my opinion) as determined in payor medical policies and coverage determinations

Ambulance Fees

1. Patient's condition - medically indicated / contraindicated
2. Medical Necessity as determined by CMS
3. Use of licensed personnel as a determinant of fees
4. Non-covered ambulance services
5. Transportation to or from one hospital or medical facility to another hospital or medical facility, skilled nursing facility, or free-standing dialysis center in order to obtain medically necessary diagnostic or therapeutic services
6. Mileage
7. Waiting time
8. Necessary equipment and supplies as determinant of fees
9. Supplies (bundled / unbundled, Date of Service and applicable standards)

Trauma Activation Fees

- CDC Guidelines for Field Triage of Injured Patients: Recommendations of the National Expert Panel on Field Triage
- County and Provider standards for Triage and documentation for Trauma Activation

Anesthesiology Fees

1. ***Time unit*** *intervals, or fraction thereof, starting from the time the physician begins to prepare the patient for induction and ending when the patient may safely be placed under post-operative supervision and the physician is no longer in personal attendance. Actual time units will be paid and are not to be rounded.*
2. ***Base Units*** *and their values are described by industry regulatory and standards bodies*
3. **Anesthesia Conversion Factors** for geographic adjustments
4. *Industry best practices for billing and coding*

CV ATTACHMENT 14 – Staff and Operational Policies for Healthcare Providers

Certification Review Process Guidelines and Best Practices:
Health Care Staffing Services Certification, Personnel File Review, Joint Commission Standards [3]:

1. Current licensure, certification, or registration required by the state, the firm, or customer from primary sources
2. Education and training associated with residency or advanced practice, experience, and competency appropriate for assigned responsibilities
3. Clinical work history/references
4. Initial and ongoing evaluation of competency
5. Information on criminal background per law, regulation, and customer requirements
6. Compliance with applicable health screening and immunization requirements established by the firm or customer
7. Information on sanctions or limitations against an individual's license is reviewed upon hire, and upon reactivation or expiration.
8. For individuals who are practicing as Licensed Independent Practitioners, in addition to the aforementioned requirements, the firm performs the following according to law, regulation, and firm policy: Voluntary and involuntary relinquishment of any license or registration is verified and documented
9. Voluntary and involuntary termination of *hospital* medical staff membership is verified and documented
10. Any evidence of an unusual pattern or an excessive number of professional liability actions resulting in a final judgment against the applicant is investigated and documented
11. Documentation that the staff person has received orientation from the organization

[3] For a health care organization to participate in and receive payment from the Medicare or Medicaid programs, it must meet the eligibility requirements for program participation, including a certification of compliance with the Conditions of Participation (CoPs) or Conditions for Coverage (CfCs), which are set forth in federal regulations. The certification is based on a survey conducted by a state agency on behalf of the federal government, the Centers for Medicare & Medicaid Services (CMS) or a national accrediting organization, such as The Joint Commission, that has been approved by CMS as having standards and a survey process that meets or exceeds Medicare's requirements. Health care organizations that achieve accreditation through a Joint Commission deemed status survey are determined to meet or exceed Medicare and Medicaid requirements.

CV ATTACHMENT 15 – Medical Device Approvals for Specific Purpose, Embedded Systems Development and Testing for Market, Pharmacovigilance for FDA Adverse Event Reporting

I. A **510**(**k**) premarket submissions to FDA to demonstrate that device to be marketed safe and effective, that is, substantially equivalent, to a legally marketed device (21 CFR 807.92(a)(3)) that is not subject to Premarket approval (PMA):

II. Device predicates as it pertains to FDA approval for specific purpose

- intended use
- technological characteristics vs. predicate;
- technological characteristics and the information submitted to FDA

  - does not raise new questions of safety and effectiveness
  - demonstrates that device is at least as safe, effective as predicate

III. Audits of healthcare providers and claims with respect to approved devices matched to medically necessary procedures:

a. Frequencies and bandwidths applicable to cardiac and brain diagnostic monitoring (ECG, EKG, EEG) and applicable medical procedure codes
b. Independent Diagnostic Testing Facility form CMS-855B device inventories
c. CPT codes matched to devices, procedure billing timelines

IV. Performance Qualification (PQ), IQ (Installation Quality), Operational Qualification (OQ)
a. Led embedded systems software team
b. Coordinated regulatory affairs work, liaison regarding IQ/OQ/PQ process

[i] Bioethics is the study of ethical, legal, and social issues raised by advances in biology and medicine including Paternalism and Genetic Testing for Disease.

[ii] Although the name ‘health informatics’ only came into use in about 1973 (Protti 1995) it is a study that is as old as healthcare itself. It was born the day that a clinician first wrote down some impressions about a patient’s illness, and used these to learn how to treat their next patient. The world is aging and there are increasing numbers of people with chronic disease; it is recognized that

the only sustainable option is planning and delivery of healthcare through technology innovation. Biomedical Informatics seeks to discern the difference between data, information, knowledge and wisdom by increasing sharing and comprehension. Professor Enrico Coiera of the Macquarie University argues that health informatics is the logic of healthcare. Dr. Mark Musen MD PhD Professor, Medicine - Biomedical Informatics Research at Stanford points out that that digital information has made knowledge infinitely larger for clinicians, and they are now are in a knowledge management crisis – getting the right information at the right time is the challenge.

[iii] Training delivered by MD, board certified orthopedic surgeon and AHIMA certified trainer who advised CMS in all 50 states, AHIMA certified inpatient coder and chart auditor, AAPC certified outpatient coder and chart auditor

[iv] Used in Medicare Part C (Medicare Advantage "MAO") Accountable Care (ACO) organizations

[v] Training delivered by MD, board certified orthopedic surgeon who advised CMS in all 50 states

[vi] Training delivered by Radiology Certified Coder (RCC), Certified Interventional Radiology Cardiovascular Coder **(**CIRCC), Certified Professional Coder (CPC) credentialed instructor

[vii] American Academy of Professional Coders (AAPC)

[viii] Training delivered by National Association of Rehabilitation Providers (NARP) trainer

[ix] Health Care Incentives Improvement Institute, HC3i

EXHIBIT D

Expert Witness Michael F. Arrigo – Cases Where Testimony has been Provided
Updated October 9, 2017

Key: (P) = retained by plaintiff, (D) = retained by defense (R) = retained by Relator

Michael F. Arrigo Expert Witness Litigation Experience

Cases Where Expert has Provided Testimony

October 9, 2017

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Federal Cases

- (R) U.S. and California ex rel. Julie Macias v. Pacific Health et al

Case CV-12-00960 RSWL Expert report July 2017. *Provide* an opinion of the amount of damages for both Medicare Part A and Part B and Medi-Cal based on potential fraud, improper patient referrals and anti-kickback violations, cost report fraud, and claims submitted for services provided by physicians and clinical staff for a free-standing psychiatric hospital and a hospital that was designated as a Disproportionate Share Hospital ('DSH'). Basis of opinions: analysis of over 1 million claim files, patient records and supporting documents, use of industry best practices and guidelines; The U.S. Department of Health and Human Services Centers for Medicare and Medicaid (CMS) views health care providers as vital in protecting the integrity of the Medicare Program by submitting accurate claims, maintaining current knowledge of Medicare billing policies, and ensuring all documentation required to support the medical need for the service rendered is submitted when requested by the MAC. Medical Necessity standards, "In addition to correct claims completion, Medicare coverage and payment is contingent upon a determination that an item or service:

• Meets a benefit category;
• Is not specifically excluded from coverage; and
• Is reasonable and necessary.[1]

[1] *Medicare Billing: 837I and Form CMS-1450*, source: U.S. Department of HHS, Centers for Medicare and Medicaid. https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/837I-FormCMS-1450-ICN006926.pdf

Expert Witness Michael F. Arrigo – Cases Where Testimony has been Provided
Updated October 9, 2017

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- (P) Jenee Hill on behalf of herself and all others v United Healthcare Insurance

United States District Court, Central District of California, Southern Division. Case SACV15-00526 DOC (RNBx). Declaration March 6, 2017 in support of Plaintiff's reply to opposition to renewed motion to certify case as a class action. Opinions regarding the function of Utilization Management best practices and regarding health plan industry best practices, generally accepted industry standards and customary guidelines followed by health plans in the normal course of business processes, and information technology with respect to UHIC's ability to identify members for which it has denied requests for prior authorization for a surgical procedure associated with CPT medical code 22857, health plan H-Plan identifiers, and Medical Loss Ratio reporting.

- (P) Confidential v. Confidential in matter before Federal Trade Commission

Preparation for litigation filings in California, New York, Florida, Texas State Attorneys General - Estimates of financial impact on U.S. health population under fee for service Medicine and health insurance reimbursement rates under both fee for service medicine and risk adjusted value based care, and how rates are set based on Computer Assisted Coding and the Affordable Care Act. Litigants are two of the largest healthcare firms in America with market capitalizations of over $10 billion. Medical coding and economics healthcare expert consultant for landmark litigation; worked directly with former RAND Economists, Jonathan Schiller at Boies Schiller and Flexner LLP re provider ICD-9, CPT and ICD-10 medical coding and billing as provided for in 45 CFR 162.1002 that adopted the ICD-10-CM and ICD-10 PCS code sets as HIPAA standards. Prepared for expert testimony which counsel anticipated would go before Commissioner Brill or Ramirez regarding functions of encoder software, computer assisted coding, Meaningful Use of Electronic Health Records under the ARRA HITECH Act, access to data as precursor to computer assisted coding, anti-trust and macroeconomics of care in health plans based on data interoperability; consideration of IT switching costs, payor-provider contracting practices and

Expert Witness Michael F. Arrigo – Cases Where Testimony has been Provided
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economics; preparation for expert report and Daubert hearing; case settled and sealed. Expert report. Due to the terms of the settlement agreement, the case is sealed and I am not permitted to disclose the names of the litigants.

- (D) U.S. Attorney General v. Confidential Hospital System in Ohio

Prepare and deliver testimony before AUSA, OIG, HHS and FBI re: investigation into Meaningful Use of Electronic Health records (ONC certification of software and CMS, Medicaid Attestations) to defend client against potential litigation related to False Claims Act.

  - 45 CFR §170.314 (subsections); 45 CFR §170.304 electronic health record certification criteria (Meaningful Use)
  - HIPAA Privacy and Security Assessment
  - 31 U.S.C. § 3729. (a) False Claims Act with respect to IT systems, processes and people to maintain accurate records.

- ('R) United States Ex. Rel. Manijeh Nikakhtar MD v. Mission City, Nick Gupta

CV 12-3692-PSG (SHX) - United States District Court, Central District of California. Expert report 2015. Opinion re: industry best practices and guidelines to comply with Section 10501(i)(3)(B) of the Affordable Care Act, and whether data reporting under the ACA is also a financial matter of reimbursement for both CMS / Medicare and California State Medi-Cal during the transition from the All-Inclusive Rate Reimbursement (AIRR) to a new Prospective Payment System (PPS) for Federally Qualified Health Centers (FQHC) and any differences in reimbursement based on national and regional standards and unit of work measures called Relative Value Units (RVUs). Evaluation of Freedom of Information Act (FOIA) obtained materials regarding FQHC compliance to U.S. HHS / Health Resources and Services (HRSA) standards and Medicare Part C reimbursement under risk adjustment scenarios. Evaluation and management (E&M), pathology, medication management fees and other coding and billing regulations and industry best practices. Patient population includes skilled nursing, behavioral health, ambulatory settings.

Expert Witness Michael F. Arrigo – Cases Where Testimony has been Provided
Updated October 9, 2017

Key: (P) = retained by plaintiff, (D) = retained by defense (R) = retained by Relator

- (D) United States Ex. Rel. v. Michael Mirando and Holter Labs – CASE NUMBER CR 16-0215 - United States District Court, Central District of California. Opinion re: Damages calculations. Expert report March 2016. Damages hearing August 2017. Independent Diagnostic Testing Facility (IDTF), use of FDA Approved devices for ECG and EEGs, associated CPT codes, patient charts, government methodologies. Damages calculations for potential sentencing and restitution. Examination of FDA 510(k) forms, frequency sampling rates vs. comparable marketed devices for ECG and EKG. Statistical sampling of patient charts, projected accuracy in Government's methodology compared to sample sizes required for 95% to 99% certainty ('beyond reasonable doubt') vs. 51% 'reasonable degree of certainty.' Produce analytics of claims data, patient referrals for damages calculations. Medical procedures included:

  95812 - Electroencephalogram (EEG) extended monitoring; 41-60 minutes
  95813 - Electroencephalogram (EEG) extended monitoring; greater than 1 hour
  95816 - Electroencephalogram (EEG); including recording awake and drowsy
  95819 - Electroencephalogram (EEG); including recording awake and asleep
  95822 - Electroencephalogram (EEG); recording in coma or sleep only
  95827 - Electroencephalogram (EEG); all night recording
  95950 - Monitoring for identification and lateralization of cerebral seizure focus, electroencephalographic (e.g., 8 channel EEG) recording and interpretation, each 24 hours
  95951 - Monitoring for localization of cerebral seizure focus by cable or radio, 16 or more channel telemetry, combined electroencephalographic (EEG) and video recording and interpretation (e.g., for presurgical localization), each 24 hours
  95953 - Monitoring for localization of cerebral seizure focus by computerized portable 16 or more channel EEG, electroencephalographic (EEG) recording and interpretation, each 24 hours, unattended.

- (P) *Allstate v Confidential Defendants*

Damages report November 2015. Michigan retained as expert to evaluate nationwide diagnostic imaging reimbursement damages for professional component (PC) and

technical component (TC) as well as RVUs focusing on Magnetic Resonance Imaging (MRI) Usual, Customary and Reasonable pricing, CPT coding and billing and resulting charges, and supporting clinical data - Criteria for determining reasonable charges 45 CFR §405.502; Michigan State automobile insurance (no-fault). No case filed at time of expert report.

State Cases

- (D) San Francisco Spine Surgeons, LLC v. Claim Works LLC.
  JAMS Reference No. 1110018697, hearing held October 2017 in San Jose, California (Ambler, Arb). Deposition and testimony at hearing. Loss / damages calculations opinions in a dispute between a health care provider and billing company. Analysis of thousands of lines of claim data using industry best practices to determine reliability of the data for damages / loss calculations. Opine re: duties of health care provider and billing company based on knowledge training education and experience, industry best practices and guidelines and U.S. H.H.S. Office of Inspector General (OIG) guidance for third-party billing relationships. Prepare rebuttal to expert on proper medical coding, billing and loss / damages calculations. Certified as an expert by Judge ambler, stipulated to by counsel for both litigants.

- (P) HITECH Medical Consulting v. NextCare

  Case No. CV2015-00435D Superior Court of the State of Arizona, County of Maricopa. Trial November 2016. Breach of contract, Unjust Enrichment, Contractual Bad Faith involving consulting firm's implementation of Electronic Health Records in an effort to comply with the ARRA HITECH Act of 2009, Meaningful Use, and HIPAA Standards. Retained to educate attorneys and ultimately the trier of fact regarding the Electronic Health Records, HITECH, and HIPAA, what the implementation and compliance process is, meaningful use core measures and menu measures, quality reporting, meaningful use audits, false information and risks of false claims act. Explain what patient engagement, smoking status, inoculations, clinical decision support patient

Expert Witness Michael F. Arrigo – Cases Where Testimony has been Provided
Updated October 9, 2017

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education materials are and why relevant to compliance with Meaningful Use. Discuss certification process for Electronic Health Records and billing with respect to medical diagnosis, medical procedures and associated medical codes. Discuss role of U.S. HHS Centers for Medicare and Medicaid, Office of National Coordinator, Regional Extension Centers in achieving Meaningful Use. Opinions regarding implementation best practices, whether HITECH Med Consulting met best practices, attestation attempts, failures, and success rates as reported by U.S. HHS / CMS and why this is relevant. Some relevant statutory requirements of the case involving my testimony included but were not limited to:

- 45 CFR §170.314 (subsections); 45 CFR §170.304 electronic health record certification criteria (Meaningful Use)
- HIPAA Privacy and Security Assessments and HITECH Act to ensure the privacy and security and safeguarding of information.
- Accuracy of clinical information
- 31 U.S.C. § 3729. (a) False Claims Act with respect to IT systems, processes and people to maintain accurate records.
- (D) SF Spine v. Claimworks JAMS Reference No. 1110018697

  Rebuttal expert regarding damages in a dispute between a physician practice and their outsourced medical billing company regarding damages, industry best practices for medical billing companies and the duties of health care providers in facilitating and maximizing billing reimbursements with third party billing companies. Basis in addition to knowledge training education and experience including U.S. HHS OIG Guidelines for third party billing companies, claims processing and denials, reasons for denials and whether those denials are likely caused by billing company or provider. Deposition testimony June12, 2017. Arbitration June 2017.

- (D) Billrite billing solutions, Inc. Spine and & Nerve Diagnostic Center.

Expert Witness Michael F. Arrigo – Cases Where Testimony has been Provided
Updated October 9, 2017

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34-2014-00166608 SUPERIOR COURT OF THE STATE OF CALIFORNIA COUNTY OF SACRAMENTO- serve as expert consultant regarding billing practices and HIPAA Privacy and Security practices in a case involving outsourced medical billing. Opinions regarding 45 CF § 164.402(1) definition of Breach, exclusions for good faith and inadvertent disclosures; 45 CFR 160.103(4)(3) definition of HIPAA Covered Entity and duties; policies and procedures to address security incidents. This includes (i) identifying and responding to suspected or known security incidents, (ii) mitigating, to the extent practicable, harmful effects of security incidents that are known to the covered entity, and (iii) documenting security incidents and their outcomes. (See 45 CFR 164.308(a)(6).) obtain satisfactory assurances to protect ePHI (164.314(a)); HITECH Act of 2009, a BA's disclosure, handling and use of PHI must comply with HIPAA Security Rule and HIPAA Privacy Rule mandates. Industry best practices and guidelines regarding Business Associates, Business Associate Agreements. Deposition February 2017.

- (D) McDermott v. Children's Hospital of Philadelphia

In the State of Pennsylvania, County of Philadelphia, Case December 2014 term, NO. 003103. Declaration 2016. Opinions regarding alleged $9.8 million in damages as future medical expenses covered generally under insurance and specifically under ACA plans, Medicaid and Medicaid waivers and under what conditions they would be covered. Review deposition testimony of opposing counsel's healthcare economist, medical experts and consider Affordable Care Act and the policies of insurance available under the ACA through the New Jersey or Pennsylvania Insurance Exchanges, Medicaid expansion, Federal Poverty Level (FPL) calculations, as well as dual eligible Medicare and Medicaid post age 65, Medicaid under a §1915(c) of the Social Security Act, Home and Community-Based Services Waiver Medicare-Medicaid Coordinated Plan (MMCP), Minimum Essential Coverage (MEC) and Essential Health Benefits (EHB), analysis as described in New Jersey Law (case venue is Pennsylvania, at the time of this update the court has determined it will be heard under New Jersey Law). Evaluate metal plan coverage by actuarial value, and cost sharing subsidies to estimate maximum out of

pocket for lifetime of patient. Compare Life Care plans and prescribed medical services to those covered in State Benchmark Plans. Determine applicability of Prohibition of Preexisting Condition Exclusions (45 CFR § 147.108) and disabilities. Discuss impact of ACA on companion laws and standards that cover disabled individuals and workplace accommodations for essential job functions, such as Rights and Responsibilities under Section 504 and the Americans with Disabilities Act (ADA) and the Olmstead Plan (including duties of 'Covered Entities' aka "HIPAA Covered Entities" which means, health care providers, payors and others). Section 1557 of the Patient Protection and Affordable Care Act (ACA), regulations regarding people with disabilities with respect to available benefits. Section 1557 is intended to "…ensure that an individual is not excluded from participating in, denied benefits because of, or subjected to discrimination as prohibited under Section 504 of the Rehabilitation Act of 1973 (disability).

- (P) Graewingholt et al v St. Josephs' Health System

  Judicial Council Coordinated Proceeding No. 4716 Master Class Action Complaint in Superior Court of the State of California, County of Orange - class action before Honorable Kim G. Dunning, 8 Dep't CX 104; filed conditionally under seal per CRC 2.551 class action litigation related to HIPAA privacy and security breach involving $8 billion health system, disclosures under HIPAA Privacy and Security, California Confidentiality of Medical Information Act (CA Civil Code §56 et seq.) Opinions: laws, best practices and procedures for privacy and security, duty to keep records protected, ICD-9, DRG, CPT coding, and pricing, and economic impact. Third party FOIA discovery with CMS, OIG, OCR, related contractors, ARRA HITECH Act and Meaningful Use attestations and payments. Review of 31,000 patient records for CMIA medical data stored in Meditech, including diagnosis codes, problem lists, lab data, BMI and other HIPAA PHI. Statutes and best practices including:

  - *HIPAA Privacy and Security (45 CFR §162.1002 45 CFR §164.308 (subsections),*
  - *45 CFR §164.410 (subsections), notification by a business associate*
  - *45 CFR §164.502 (subsections), Uses and disclosures of protected health*

information

- *45 CFR 164.512 - Uses and disclosures for which an authorization or opportunity to agree or object is not required, especially § 164.512(j)(1) Uses and disclosures to avert a serious threat to health or safety and § 164.512(j)(2-4) Use or disclosure not permitted.*
- *45 CFR §170.314 (subsections); electronic health record certification criteria (Meaningful Use)*
- *31 U.S.C. § 3729. (a) False Claims Act;*
- *California Confidentiality of Medical Information Act (CA Civil Code §56 et seq.)*
- *ARRA HITECH Act reporting procedures and documentation, attestations and stimulus funds eligibility based on evaluation of over 33 measures, information safeguards, operating procedures. Expert Report 2015.*

- *Cost expenditures based on HITECH Act Final Rule, HIPAA Final Rule in support of counsel's damages theories.*

- (D) Confidential Plaintiff v. Pasadena School District

BC 457 096 Superior Court of the State of California for the County of Los Angeles. HIPAA privacy and security, disclosures under ***HIPAA Privacy and Security***.
Opinions: laws, best practices and procedures for privacy and security, duty to keep records protected, whether there is a duty to disclose records. Relevant statutes and best practices include: 45 CFR 164.512 - Uses and disclosures for which an authorization or opportunity to agree or object is not required, especially § 164.512(j)(1) Uses and disclosures to avert a serious threat to health or safety and § 164.512(j) (2-4) Use or disclosure not permitted (Tarrasoff standard). Deposition, 2015.

Expert Witness Michael F. Arrigo – Cases Where Testimony has been Provided
Updated October 9, 2017

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- (P) R.D., vs. Providence Health Services et al,

14-2-33747-7 SEA in The Superior Court of the State of Washington in and for the County of King – HIPAA privacy and security breach involving alleged unauthorized breach of HIV diagnosis at multi-billion-dollar health system, disclosures under HIPAA Privacy and Security. Examine EPIC EMR and Onbase electronic health record Meaningful Use compliance according to industry best practices and guidelines. Opinions: laws, best practices and procedures for privacy and security, duty to keep records protected, related contractors, ARRA HITECH Act and Meaningful Use attestations and security best practices. Potential citations of statutes and cases including:

- HIPAA Privacy and Security (45 CFR §162.1002 45 CFR §164.308 (subsections)),
- 45 CFR §164.410 (subsections), notification by a business associate
- 45 CFR §164.502 (subsections), Uses and disclosures of protected health information
- 45 CFR §170.314 (subsections); electronic health record certification criteria (Meaningful Use)
- 31 U.S.C. § 3729. (a) False Claims Act;
- ARRA HITECH Act reporting procedures and documentation, attestations and stimulus funds eligibility based on evaluation of over 33 measures, information safeguards, operating procedures.
- Joint Commission standards for healthcare staffing firms, Medicare and Medicaid eligibility Conditions of Participation (CoPs) or Conditions for Coverage (CfCs)
- Wash. Admin. Code § 246-455-080 Security and Release of Reported Hospital Patient Discharge Data

(2) … security and system safeguards to prevent and detect unauthorized access, modification, or manipulation of individually identifiable health information. Accordingly, the safeguards will include:

(a) Documented formal procedures for handling the information;

(b) Physical safeguards to protect computer systems and other pertinent equipment from intrusion;

(c) Processes to protect, control and audit access to the information;

(d) Processes to protect the information from unauthorized access or disclosure when it is transmitted over communication networks;

(e) Processes to protect the information when it is physically moved from one location to another;

(f) Processes to ensure the information is encrypted when:

(i) It resides in an area that is readily accessible by individuals who are not authorized to access the information (e.g., shared network drives or outside the agency data centers);

(ii) It is stored in a format that is easily accessible by individuals who are not authorized to access the information (e.g., text files and spreadsheets);

- Wash. Rev. Code § 70.02.170 Civil remedies – Declaration 2016.

- (D) Confidential Plaintiff (Jane Doe) v. Brigham and Women's Hospital.

C.A. No. 2014-0007-B Suffolk Superior Court, Massachusetts. Evaluate whether best practices in HIPAA Privacy and Security were used to prevent HIPAA privacy breach. Opinions: laws, best practices and procedures for privacy and security, duty to keep records protected. Third party FOIA discovery with CMS, OIG, OCR, related contractors, ARRA HITECH Act and ***Meaningful Use attestations patient portal security best practices****. Potential citations of statutes and cases including:*

- *Massachusetts State Statute: Standards for the Protection of Personal*

Expert Witness Michael F. Arrigo – Cases Where Testimony has been Provided
Updated October 9, 2017

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Information of Residents of the Commonwealth, as set forth in M.G.L. c. 93H and 201 C.M.R. 17.00, et seq HIPAA Privacy and Security (45 CFR §162.1002 45 CFR §164.308 (subsections)),

- *45 CFR §164.502 (subsections), Uses and disclosures of protected health information*
- *45 CFR §170.314 (subsections); electronic health record certification criteria (Meaningful Use)*
- *Declaration 2016*

- (P) Jane Doe vs United Medical Center and Innovative Staffing Solutions. Case No. 2015 CA 003716 B in Superior Court for the District of Columbia. Opinions regarding industry best practices and guidelines for health care providers and the Certification Review Process / Health Care Staffing Services Certification Personnel File Review. Joint Commission standards for healthcare staffing firms, Medicare and Medicaid eligibility Conditions of Participation (CoPs) or Conditions for Coverage (CfCs). Declaration 2016.

1. Current licensure, certification, or registration required by the state, the firm, or customer from primary sources
2. Education and training associated with residency or advanced practice, experience, and competency appropriate for assigned responsibilities
3. Clinical work history/references
4. Initial and ongoing evaluation of competency
5. Information on criminal background according to law, regulation, and customer requirements
6. Compliance with applicable health screening and immunization requirements established by the firm or customer
7. Information on sanctions or limitations against an individual's license is reviewed upon hire, and upon reactivation or expiration. For
8. individuals who are practicing as Licensed Independent Practitioners, in

addition to the aforementioned requirements, the firm performs the following according to law, regulation, and firm policy: Voluntary and involuntary relinquishment of any license or registration is verified and documented

9. Voluntary and involuntary termination of hospital medical staff membership is verified and documented
10. Any evidence of an unusual pattern or an excessive number of professional liability actions resulting in a final judgment against the applicant is investigated and documented
11. Documentation that the clinical staff person has received orientation from the organization

- (P) Jessica Umstead, Plaintiff v. Mercy Hospital, Cedar Rapids Iowa

In the Iowa District Court in and for Linn County. No. LACV 086191. Declaration 2017. Opinions – whether Mercy Hospital, Cedar Rapids ("Mercy") is a HIPAA Covered Entity ("CE") and is subject to Federal and state regulations, including the HIPAA Privacy and Security Rules and the ARRA HITECH Act and Administrative Safeguards, Physical Safeguards, Technical Safeguards, Documented Organizational Policies, Procedures, whether Workforce member of a CE, has duties under the both HIPAA and the HITECH Act Safeguards, CE policies and training protocols, corrective actions, information access controls, and supervision of its workforce. Patients reasonable expectation that their sensitive Protected Health Information ("PHI") will be kept private, damages that are commonly awarded to patients whose PHI accessed or are released without authorization, Mercy's policies and procedures are in direct conflict with statutes, industry best practices and guidelines to protect PHI. Whether Mercy was met standards mandated by Behavioral Health Unit. 42 CFR Part 2 and Iowa Code 228 which provides specific protection from disclosure of mental health information and requires that upon disclosure, the patient is notified that an unauthorized disclosure of mental health information is unlawful, and that civil damages and criminal penalties may be applicable to the unauthorized disclosure of mental health information, corrective action including

Workforce member sanctions. *See* § 164.308(a)(1)(ii)(A)) and SANCTION POLICY § 164.308(a)(1)(ii)(C). Violation of the Minimum Necessary Standard. (*See* 42 CFR 164.502(b)); Failure to detect, prevent and correct security violations. §164.308(a)(1), 2013 HIPAA Omnibus Final Rule, Access Control Standard provided for in § 164.312(a)(1) by failing to ensure access controls only provided the minimum necessary access. Whether Electronic Health Record system was not configured to perform an Automatic Logoff per §164.312(a)(2)(iii)) duty to mitigate harm but failed to do so. (*See* 45 C.F.R. § 164.402 (Subpart D) and whether there was a violation of Iowa Code Section 22.7 regarding confidentiality of medical records and Iowa Code 228 regarding protection from disclosure of mental health information.

- (P) Jacqueline Krouse v. Avera Health and Chris Krouse

Case 15-3083 State of South Dakota, County of Minnehaha, Second Judicial Circuit. Declaration 28th of February 2017, Deposition May 2017. Opinions – whether Avera Hospital, Cedar Rapids ("Avera") is a HIPAA Covered Entity ("CE") and is subject to Federal and state regulations, including the HIPAA Privacy and Security Rules and the ARRA HITECH Act and Administrative Safeguards, Physical Safeguards, Technical Safeguards, Documented Organizational Policies, Procedures, whether Workforce member of a CE, has duties under the both HIPAA and the HITECH Act Safeguards, CE policies and training protocols, corrective actions, information access controls, and supervision of its workforce. Patients reasonable expectation that their sensitive Protected Health Information ("PHI") will be kept private, damages that are commonly awarded to patients whose PHI accessed or are released without authorization, Avera's policies and procedures are in direct conflict with statutes, industry best practices and guidelines to protect PHI. Whether Avera was met standards mandated by Behavioral Health Unit. 42 CFR Part 2 Workforce member sanctions. *See* § 164.308(a)(1)(ii)(A)) and SANCTION POLICY § 164.308(a)(1)(ii)(C). Violation of the Minimum Necessary Standard. (*See* 42 CFR 164.502(b)); Failure to detect, prevent and correct security violations. § 164.308(a)(1), 2013 HIPAA Omnibus Final Rule, Access Control Standard provided for in § 164.312(a)(1) by failing to ensure access controls only provided the minimum

necessary access. Whether Electronic Health Record system was not configured to perform an Automatic Logoff per §164.312(a)(2)(iii)) duty to mitigate harm but failed to do so. (*See* 45 C.F.R. § 164.402 (Subpart D).

- (P) FT v. Children's Mercy Hospital

Case No.: 1616-CV01466. Deposition April 2017. Opinions and basis:

Principles Statutes Industry Best Practices and Guidelines

1. The HIPAA Breach Notification Rule, 45 CFR §§ 164.400-414, requires HIPAA covered entities and their business associates to provide notification following a breach of unsecured protected health information.
   a. A breach is, generally, an impermissible use or disclosure under the Privacy Rule that compromises the security or privacy of the protected health information. An impermissible use or disclosure of protected health information is presumed to be a breach unless the covered entity or business associate, as applicable, demonstrates that there is a low probability that the protected health information has been compromised based on a risk assessment of at least the following factors:
      i. The nature and extent of the protected health information involved, including the types of identifiers and the likelihood of re-identification;
      ii. The unauthorized person who used the protected health information or to whom the disclosure was made;
      iii. Whether the protected health information was actually acquired or viewed; and
      iv. The extent to which the risk to the protected health information has been mitigated.
2. Provider's compliance to HIPAA Privacy and Security Rules and the HITECH Act related to the breach, including
      a. Providers' Security Incident Procedures provided for in § 164.308(a)(6) [i] [ii]

Expert Witness Michael F. Arrigo – Cases Where Testimony has been Provided
Updated October 9, 2017

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b. Provider's methods for conducting a Breach Evaluation regarding access of Plaintiff medical records [iii]

c. Provider's Response and Reporting **results** of the Breach Evaluation[iv] regarding access of Plaintiff's medical records provided for in § 164.308(a)(6)(ii)[v]

d. Provider's identification of any for failures to follow industry best practices and guidelines to obtain reasonable assurances [vi] and a Business Associate Agreement from any subcontractors jointly responsible for maintaining any breached system(s).[vii viii ix]

3. Prior reports and complaints against Provider regarding improper access to patients' medical records;

4. American Recovery and Reinvestment Act (ARRA) Health Information Technology for Economic and Clinical Health Act (HITECH) related issues, including compliance with associated federal rules and regulations;

a. Provider's Risk Analysis, Risk Management,[x] Sanction Policy and Information System Review, and annual updates to the Risk Analysis [xi xii xiii] in general for the year prior, the year of, and the year after the breach.

b. Provider's Information Systems Activity Review (§ 164.308(a)(1)(ii)(D)[xiv]

c. Provider's findings from Risk Analysis, specifically:[xv]

i. What security measures were used to protect ePHI during transmission?

ii. Did the risk analysis identify scenarios that may result in modification to ePHI by unauthorized sources during transmission?

d. Provider's audit controls under § 164.312(b) that monitor access of electronic protected health information (ePHI) [xvi] including implementation of hardware, software, and/or procedural mechanisms

Expert Witness Michael F. Arrigo – Cases Where Testimony has been Provided
Updated October 9, 2017

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that record and examine activity in information systems that contain or use electronic protected health information[xvii] specifically:

i. What audit control mechanisms were reasonable and appropriate to implement so as to record and examine activity in information systems that contain or use ePHI?

ii. What are the audit control capabilities of information systems with ePHI?

iii. Did the audit controls implemented allow the organization to adhere to policy and procedures developed to comply with the required implementation specification at § 164.308(a)(1)(ii)(D) for Information System Activity Review?

e. Access Control Standard § 164.312(a)(1) – enabling authorized users to access the minimum necessary information needed to perform job functions. [xviii]

f. Information Access Management provided for in § 164.308(a)(4)[xix]

g. Person or Entity Authentication provided for in § 164.312(d) [xx]

h. Provider's compliance with Security Awareness and Training including Security Reminders, Log-in Monitoring provided for in § 164.308(a)(5). [xxi]

i. Workforce Security as provided for in § 164.308(a)(3) [xxii]

j. Authorization and Supervision as provided for in § 164.308(a)(3)(ii)(A) [xxiii] Specifically:

i. Are detailed job descriptions used to determine what level of access the person holding the position should have to ePHI?

ii. Who has or should have the authority to determine who can access ePHI, e.g., supervisors or managers?

iii. Are there similar existing processes used for paper records that could be used as an example for the ePHI?

Expert Witness Michael F. Arrigo – Cases Where Testimony has been Provided
Updated October 9, 2017

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k. Workforce Clearance Procedure as provided for in § 164.308(a)(3)(ii)(B)[xxiv]
   i. Are there existing procedures for determining that the appropriate workforce members have access to the necessary information?
   ii. Are the procedures used consistently within the organization when determining access of related workforce job functions?

l. Termination Procedures as provided for in § 164.308(a)(3)(ii)(C) [xxv]
   i. Do the termination policies and procedures assign responsibility for removing information system and/or physical access?
   ii. Do the policies and procedures include timely communication of termination actions to insure that the termination procedures are appropriately followed?

5. Documentation of Provider's policies and procedures demonstrating compliance during the calendar year of the breach with Joint Commission Health Care Staffing Services Certification (HCSS) [xxvi] including:
   a. that the staff person has received orientation from the organization.
   b. initial and ongoing evaluation of competency
6. Information technology related issues, including how the electronic health record system or supporting systems at rest (i.e. hospitals Longitudinal Medical Record System ('LMR') or Clinical Data Repository ('CDR') and integrated patient portal and/or Provider's medical records storage system(s) work, including security and monitoring features, access limitations, and notification procedures regarding improper access;
7. Provider's knowledge regarding access of Plaintiff's medical records, including what records were accessed, the length of time or number of times they were accessed, what information was viewed, and the investigation Provider performed; [Massey

deposition stated no actions taken, no follow up with the Police, no mitigation, no anti-identity theft offering to Plaintiff]

8. Provider's knowledge regarding training that is required or conducted for temporary or permanent medical records IT staff, reviewers such as coders and auditors, and clinical staff.

- *(D) Paulette Diaz, et al, vs. MDC Restaurants, LLC et al;*

Case A 701633. Deposition 2016. Department XV class action complaint in the Eighth Judicial District Court in and for Clark County, State of Nevada. Served as rebuttal expert in a case concerning what constitutes "health insurance," qualified health insurance plans, and those expenses covered generally under insurance and specifically under ACA plans, Medicaid and Medicaid waivers and under what conditions they would be covered. Apply national perspective to health insurance coverage under The Nevada Administrative Code§ 608. and §608.104, Nevada Labor Commissioner's regulations and opinions regarding the convolution of the Act, and a review of specific benefits offered by an employer of minimum wage workers in comparison to national industry best practices and guidelines in respect to the Patient Protection :md Affordable Care Act ("ACA"), including Medicaid Expansion in Nevada, Minimum Essential Coverage ("MEC"), out-of-pocket limits, and Federal Poverty Level (FPL) guidelines. Areas of testimony also included the tenets of cost-sharing subsidies and minimum essential coverage (MEC), benchmark plans, generally, as well as within federal laws such as the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Employee Retirement Income Security Act of 1974 (ERISA) and related issues, including Taft-Hartley trusts and Centers for Medicare and Medicaid (CMS).

- (D) Natalie Torres v Pocatello Children and Adolescent Clinic, et al.,

Case CV-2013-1553. Declaration 2015. District Court of Sixth Judicial District of the State of Idaho, Bannock County. Expert opinion re: future medical expenses and those expenses covered generally under insurance and specifically under ACA plans, Medicaid

and Medicaid waivers and under what conditions they would be covered. Review deposition testimony of opposing counsel's healthcare economist, medical experts and consider Affordable Care Act and the policies of insurance available under the ACA through the Idaho Exchange, as well as Medicaid under a §1915(c) of the Social Security Act, Home and Community-Based Services Waiver Medicare-Medicaid Coordinated Plan (MMCP), as described in Idaho Law (IDAPA 16.03.17). Determine applicability of Prohibition of Preexisting Condition Exclusions (45 CFR § 147.108), Medicare Expansion and Health Insurance Exchanges.

- (D) *Bradley Welding v Franscali and Orthopedic Associates of Northern Illinois*

In the State of Illinois in the Circuit Court of the 17th Judicial Circuit Winnebago County, Illinois Case 12 L 323. Expert report 2016. Expert opinion re: accuracy of data for future medical expenses including pain management modalities (Ketamine Infusions, Continuous Epidural Spinal Infusion, Continuous Spinal Cord Stimulator, Dorsal Root Ganglia Stimulator) and supporting medical durable medical equipment (DME) pain management device (s). Review deposition testimony of opposing counsel's healthcare economist, medical experts and consider Affordable Care Act and the policies of insurance available under the ACA through the Illinois Exchange, Medicaid expansion, Federal Poverty Level (FPL) calculations, as well as dual eligible Medicare and Medicaid post age 65, Medicaid under a §1915(c) of the Social Security Act, Home and Community-Based Services Waiver Medicare-Medicaid Coordinated Plan (MMCP) for disabled insureds as described in Illinois Law. Opinion regarding subrogation under the Affordable Care Act. Evaluate "metal plan" (bronze, silver, etc.) coverage by actuarial value, and cost sharing subsidies to estimate maximum out of pocket for lifetime of patient. Condition Exclusions (45 CFR § 147.108).

- (P) *Giraldo v. Canta and Groceryworks.com et al*

Case CGC-15-544893 Superior Court of California, County of San Francisco. Expert report, 2016, trial appearance August 2016. Rebuttal expert regarding whether emergency

medical fees including Trauma Activation, ambulance transportation (including mileage, supplies, other fees) are reasonable customary and necessary according to industry best practices and guidelines. Specifically, evaluate the documentation by an emergency response team and whether it supports U.S. Centers for Disease Control (CDC) Guidelines for Field Triage of Injured Patients: Recommendations of the National Expert Panel on Field Triage, 2011; Federal Interagency Committee on Emergency Medical Services (FICEMS), established by Public Law 109-59, and section 10202 (*18*) California Health and Safety Code § 1371.4 a provision of the Knox-Keene Act. Provide geographic market analysis of usual customary and reasonable (UCR) fees for orthopedic, pain management, medical device (s) and supplies, medication, behavioral health, rehabilitation medical expenses; ICD-9 diagnosis, CPT outpatient procedures, HCPCS medical supplies, ambulance fee medical coding.

- (P) UCLA Medical Center v. Blue Cross Blue Shield

Arbitration with AAA case no. 722013001112. Expert report, 2015. Pre-arbitration expert consultant for mediation with JAMS reference number 1200051271. Provide expert opinion on role of Medicare Administrative Contractors (MACs) in providing reimbursement rates and the historical pricing guidance and usage of nuclear medicine codes. Provide expert opinion on reimbursement for Technical Component (TC) and Professional Component (PC) as well as Relative Value Units (RVUs) of diagnostic imaging services primarily used for Oncology (Nuclear Medicine, PET-Scan) based on specific services by CPT code.

- (P) *Rhodes v Renown*

CV14-02054 in the Second Judicial District Court of the State of Nevada in and for the County of Washoe. Expert report 2015. Patient financial services, Medical coding, usual customary and reasonable (UCR) cost of care and documentation of necessity for outpatient obstetrics surgical procedure and CPT codes, medical device (s) and supplies. Applicable State Statutes include: Uninsured patient discount (NRS 439B.260); Federal

Expert Witness Michael F. Arrigo – Cases Where Testimony has been Provided
Updated October 9, 2017

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statutes and best practices: Fair and Accurate Credit Transactions Act ("FACTA**")** Fair Credit Reporting Act **(**FCRA). FACTA §312(a), (FACTA§312(c), FCRA §623(e)(1)), FCRA §623(a)(8)); Ability of patients as consumers to dispute information with companies that report to credit bureaus; Affordable Care Act (not for profit hospitals required to offer community benefit in exchange for its tax-exempt status[2] (see Rev. Rul. 69-545, 1969-2 C.B. 117.))

- (P) *John D. Thomson v. HMC Group, Torrance Medical Center*

Et al. CV13 - 03273 D M G United States District Court, Central District of California. Expert report and deposition 2015. Expert opinion regarding hospital facility revenues for use in cost benefit analysis, damages calculations for surgical suites based on industry best practices and statutes associated with damages related to intellectual property rights litigation. Evaluation of revenues attributable to surgical suites based on Inpatient Prospective Payment System (IPPS) and Outpatient Prospective Payment System (OPPS) using defendant provided materials as well as government sources from HHS / CMS. Demonstrated expertise in statutory mandates such as Diagnosis Related Groupings (DRGs), ICD-9, ICD-10 and CPT codes. Applicable statutes include: Section 1886(d) of the Social Security Act and Title Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) P.L. 98–21, Approved April 20, 1983, 42: Public Health Part 412, Criteria for determining reasonable charges 45 CFR §405.502, 42 CFR 412.2(c)(5)). § 412.2 "Basis of payment" and 42 CFR 412.60 - DRG classification and weighting factors provides the method to calculate DRGs.

[2]"Examples illustrate whether a nonprofit hospital claiming exemption under section 501(c)(3) of the Code is operated to serve a public rather than a private interest; Revenue Ruling 56-185 modified." – IRS.gov/pub/irs-tege/rr69-545.pdf (see Rev. Rul. 69-545, 1969-2 C.B. 117.)[2]

Expert Witness Michael F. Arrigo – Cases Where Testimony has been Provided
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- (D) *Joann Hilton v. USA Logistics Carriers, LLC and Jose Juan Soto-Estrada*

Case No. C879214-J, in the 430th District Court of Hidalgo County, Texas. Expert report and deposition 2014. Usual customary and reasonable fees, coding and billing and resulting charges including CPT, MRI, CPT, ED, ambulance, emergency room (including explanation to court of Level 1, Level 2, Level 3, Level 4, Level 5 ED visits), trauma activation fees, cost of ER and OR per minute, spinal fusion procedure (orthopedic surgical), medical device (s) including surgical screws, surgical screws, supplies, chiropractic, pharmacy (NDC codes for medication), pain management, physical therapy, and other procedures; duty to mitigate costs, ambulance and non-emergency transportation costs, three-day payment rule 42 CFR 412.2(c)(5); evaluate potential merits for U.S.C. § 3729. ICD-9, CPT, DRG, HCPCS and hospital revenue coding, duty to mitigate damages under Texas statutes, Section 1886(d) of the Social Security Act and Title 42: Public Health Part 412—Prospective Payment Systems for Inpatient Hospital Services; subrogation issues.

- (D) *Raul Martinez v. Lee Ill Young*

BC489656, Superior Court of the State of California for the County of Los Angeles, Central District. Expert report 2015. Determination of Usual Customary and Reasonable (UCR) cost of care medical bills including spinal fusion surgery for orthopedics, and diagnostic imaging medical specialties. Evaluate codes and episodic groupings (DRGs), ICD-9, CPT for inpatient days, ambulatory procedures, rehabilitation, surgical procedures, supplies and device costs, Section 1886(d) of the Social Security Act and Title 42: Public Health Part 412—Prospective Payment Systems for Inpatient Hospital Services. Patient's duty to mitigate medical costs.

- (D) Jorge Uribe v. City of Maywood and Andrew Serrata

J.S.I.D. File 10-0416 L.A.S.D. URN 010-00058?3199-055 Los Angeles County District Office Bureau of Fraud and Corruption Prosecutions Justice System Integrity Division. Determination of Usual Customary and Reasonable (UCR) cost of care for approximately $500,000 in medical bills including surgery for internal injuries caused by gunshot

Expert Witness Michael F. Arrigo – Cases Where Testimony has been Provided
Updated October 9, 2017

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wounds – trauma activation fees, ambulance transportation, cardiology, orthopedics, pathology / lab tests and interpretations, and diagnostic imaging medical specialties including CT and MRI, room charges, operating room minutes, medications, anesthesia, evaluation and management (E&M). Evaluate codes and episodic groupings (DRGs) for inpatient days, ambulatory procedures, rehabilitation, surgical procedures, supplies and device costs, duty to mitigate damages. Relevant statutes, industry standards and best practice: Section 1886(d) of the Social Security Act and Title 42: Public Health Part 412—Inpatient Prospective Payment System (IPPS) for Hospital Services and customary rehabilitation charges and reimbursement.

- *(D) Billrite v Vinay M. Reddy, MD, Spine & Nerve Diagnostic Center.*

34-2014-00166608 SUPERIOR COURT OF THE STATE OF CALIFORNIA COUNTY OF SACRAMENTO. Expert report August 2016. Deposition February 2017. Provide opinion regarding industry best practices and guidelines for outsourced medical billing for pain management, electromyogram ("EMG") which are used for among other medical applications, advanced pain management, diagnostics such as Nerve Conduction Studies (NCS), Epidural Steroid Injection (ESI) and Urine Toxicology Studies for a health care provider and whether medical coding and billing was being performed in compliance with industry best practices and guidelines. Evaluate whether proper coding in compliance with California Workers' Compensation Reform Senate Bill 863 (SB 863) and the National Correct Coding Initiative (NCCI) which provides for guidelines on proper bundling of services (and, flags incorrectly unbundled services which may be due to fraud or up coding). Evaluate claims under California Workers' Compensation and California SB 863 which standardized Workers' Compensation based on Medicare billing rules; Medical Treatment Utilization Schedule (MTUS) which focus on reducing costs and utilization for procedures including chronic pain treatment, neck / upper back procedures, elbow disorders, forearm, wrist, hand, low back, knee procedures, cost of surgical screws and medical device (s).

Expert Witness Michael F. Arrigo – Cases Where Testimony has been Provided
Updated October 9, 2017

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- *(D) Rose v. Herfy's and Lee*

NO. 15-2-14145-7 SEA Superior Court of the State of Washington for King County. Expert report and deposition September 2016. Evaluate over $1.5 million in medical bills including orthopedic procedures, medical device (s) and supplies rehabilitation and skilled nursing billings. Perform regional analysis for Seattle metropolitan area on usual customary and reasonable charges from other providers; prepare declaration and expert report December 2016, Deposition January 2016. Opinions, basis: OPPS and CPT, APC codes, IPPS, DRG inpatient procedures, skilled nursing billing, rehabilitation, orthopedic supply, national and regional pricing; customary charge rates when there is a collateral source rule. Opine on the usual customary and reasonable cost of care in the Seattle market regarding over $1.2 million in medical bills. Billings spanned several years and geographic locations. Billings were for several medical specialties including inpatient, outpatient, skilled nursing and rehabilitation. Over 4,400 pages of documentation on medical supplies, rehabilitation after hospital discharges, etc. including:

1. Ambulance transportation
2. Ambulatory Surgery Center (ASC) payment models including APCs
3. Anesthesiology including anesthesia monitoring time
4. Blood gas procedures
5. Cardiology
6. CT Scans
7. Emergency medicine
8. Evaluation and Management (E&M) physician encounters
9. Home care / home care self-care education
10. Injections
11. Inpatient payment rules
12. Medications including AWP and PBM fees (Tizanidine / muscle relaxant, enoxaparin, pravastatin, insulin,
13. Operating room time and charges
14. Orthopedic surgery and physician bills
15. Outpatient payment rules and physician fee schedules
16. Pain management and pain specific medications and procedures (Ketamine, Morphine, Oxycodone, spinal stimulators)
17. Pathology including blood and other laboratory tests

Expert Witness Michael F. Arrigo – Cases Where Testimony has been Provided
Updated October 9, 2017

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18. Physical Therapy
19. Recovery / rehab room time and charges
20. Surgical room time and charges
21. Surgical screws related to orthopedic surgery
22. Trauma activation fees
23. Vascular procedures
24. Wheelchairs and other medical supplies
25. X-Rays

- *(D) Derkack v. Boyd*

NO. 15-2-18391-5 KNT SUPERIOR COURT OF THE STATE OF WASHINGTON FOR KING COUNTY. Expert declaration September 29th, 2016. Evaluate over $1.5 million in medical bills including orthopedic procedures, medical device (s) and supplies rehabilitation and skilled nursing billings. Perform regional analysis for Seattle metropolitan area on usual customary and reasonable charges from other providers; prepare declaration and expert report December 2016, Deposition January 2016. Opinions, basis: OPPS and CPT, APC codes, IPPS, DRG inpatient procedures, skilled nursing billing, rehabilitation, orthopedic supply, national and regional pricing; customary charge rates when there is a collateral source rule. Opine on the usual customary and reasonable cost of care in the Seattle market regarding over $1.2 million in medical bills. Billings spanned several years and geographic locations. Billings were for several medical specialties including inpatient, outpatient, skilled nursing and rehabilitation. Over 4,400 pages of documentation on medical supplies, rehabilitation after hospital discharges, etc. including:

1. Ambulance transportation
2. Ambulatory Surgery Center (ASC) payment models including APCs
3. Anesthesiology including anesthesia monitoring time
4. Blood gas procedures
5. Cardiology
6. CT Scans
7. Emergency medicine evaluation and management (E&M) physician encounters including

Expert Witness Michael F. Arrigo – Cases Where Testimony has been Provided
Updated August 22, 2017

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Level I (CPT 99281) Level II (CPT 99282), Level III (CPT 99283) Level IV (CPT 99284) Level V (CPT 99285) and correlating Ambulatory Procedure Codes (APCs) based on possible interventions and potential symptoms / patient conditions.

8. Evaluation and Management (E&M) physician encounters post admission, post discharge
9. Home care / home care self-care education
10. Injections
11. Inpatient payment rules
12. Medications including AWP and PBM fees (Tizanidine / muscle relaxant, enoxaparin, pravastatin, insulin,
13. Operating room time and charges
14. Orthopedic surgery and physician bills
15. Outpatient payment rules and physician fee schedules
16. Pain management and pain specific medications and procedures (Ketamine, Morphine, Oxycodone, spinal stimulators)
17. Pathology including blood and other laboratory tests
18. Physical Therapy
19. Recovery / rehab room time and charges
20. Surgical room time and charges
21. Surgical screws related to orthopedic surgery
22. Trauma activation fees
23. Vascular procedures
24. Wheelchairs and other medical supplies
25. X-Rays

Expert Witness Michael F. Arrigo – Cases Where Testimony has been Provided
Updated August 22, 2017

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- *(D) Tamie Lobin v. J.B. Hunt Transport, Inc. and Roosevelt Allen.*

AAA Arbitration No: 01-16-0000-0480. Expert report March 13, 2017. Deposition March 13, 2017. Arbitration August 2017. Review the medical billing, medical and other relevant documents and provide an opinion based on the usual customary and reasonable charges for the bills provided to me for Plaintiff's past care in 2014 – 2017 in Dallas, Texas; opinion of the maximum out of pocket cost (meaning the costs borne by the Plaintiff rather than insurance) of care for the Plaintiff if receiving medical benefits as a disabled person from Texas Medicaid, Medicaid Waivers and programs for those with disabilities, and an opinion of the maximum out of pocket cost of care for the Plaintiff if receiving medical benefits from an Affordable Care Act (ACA) qualified health plan, or a conforming Taft-Hartley labor management trust fund "grandfathered" health plan under the ACA. Based on the life care plan from Plaintiff, provide an opinion based on the criteria above regarding future costs of care, including Medicare coverage on and after age 65, and conduct a market study in Dallas, Texas to confirm with reasonable certainty whether Plaintiff has access to covered benefits for her medical costs, and whether contracted health care providers are easily accessible within a 25-mile radius of his home who offer care for his insured benefits. Basis included Inpatient Prospective Payment Rule (IPPS), Outpatient Prospective Payment Rule, DRG, CPT code values, Medicare Geographic Adjustment Factors (GAF), Medicaid reimbursement and claims, clinical documentation in support of claims.

Expert Witness Michael F. Arrigo – Cases Where Testimony has been Provided
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- *(P) Medical Acquisition Company, Inc. v. Southwest Law Center et al*

Case number BC585918 Superior Court of the State of California, County of Los Angeles. Deposition July 2015. Review the medical billing, medical and other relevant documents and provide an opinion based on the usual customary and reasonable charges for the bills provided to me for Plaintiff's past care in in the Los Angeles, Orange County, and San Francisco Core Based Statistical Areas (CBSA) markets; (meaning the costs that should be borne by the Plaintiff rather than insurance). Counsel provided specific instructions: "…in the *Katiuzhinsky*, case, the court dealt with the uninsured plaintiff treated on liens. There the appellate court refused to speculate about factoring or future lien write downs and found that the plaintiff was not prevented from recovering the full amount of bills as long as they were legitimately incurred and plaintiff remained responsible for the full amount." Counsel also explained that, "… in the *Bermudez*, case, the court again dealt with the plaintiff with no medical insurance. There it found the billed amounts relevant and admissible in the uninsured context, subject to plaintiff's burden of proof that they are reasonable and customary." Applied a methodology that reviews charges, which is defined as "The dollar amounts a provider sets, or 'bills' for services rendered ..." Basis included, Outpatient Prospective Payment Rule, DRG, CPT code values, Medicare Geographic Adjustment Factors (GAF), whether medical procedures were unbundled using the National Correct Coding Initiative (NCCI) which uses software algorithms to compare combinations of medical procedure CPT billing codes, place of service, date of service to identify disallowable unbundling, Medically Necessary procedures (basis NCCI) which can be employed using software algorithms to compare combinations of medical procedure CPT billing codes and diagnosis codes to identify those medical procedures that may be un-necessary.

[i] The Security Final Rule defines "security incident" in §164.304 as "the attempted or

successful unauthorized access, use, disclosure, modification, or destruction of information or interference with system operations in an information system.

[ii] (a) A covered entity must, in accordance with § 164.306:
(6)(i) Standard: Security incident procedures. Implement policies and procedures to address security incidents.
(ii) Implementation specification: Response and Reporting (Required).
Identify and respond to suspected or known security incidents; mitigate, to the extent practicable, harmful effects of security incidents that are known to the covered entity; and document security incidents and their outcomes.

[iii] The HIPAA Final Rule also known as "HIPAA Omnibus Rule" provides Covered Entities make a determination of whether PHI was "compromised" based on a four factor breach evaluation (*See* 45 CFR Parts 160 and 164 modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under the Health Information Technology for Economic and Clinical Health Act and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules; Business Associate and Business Associate Agreement published January 25, 2013 and effective March 26, 2013).

[iv] The HIPAA Security Rule requires covered entities to implement policies and procedures to address security incidents. This includes (i) identifying and responding to suspected or known security incidents, (ii) mitigating, to the extent practicable, harmful effects of security incidents that are known to the covered entity, and (iii) documenting security incidents and their outcomes. (See 45 CFR 164.308(a)(6).)

[v] "Identify and respond to suspected or known security incidents; mitigate, to the extent practicable, harmful effects of security incidents that are known to the covered entity; and document security incidents and their outcomes."

[vi] § 164.308(b)(4) provides, "Document the satisfactory assurances required by paragraph

(b)(1) [the Business Associate Contracts and Other Arrangements] of this section through a written contract or other arrangement with the business associate that meets the applicable requirements of §164.314(a) [the Organizational Requirements].

[vii] Since the April 14, 2003 HIPAA Privacy Rule deadline, **Covered Entities** have been **required** to obtain satisfactory assurances (164.314(a)) that the business associate will appropriately safeguard health information. A covered entity that violates satisfactory assurances will be in non-compliance with the standards and requirements (164.314(a)).

[viii] The HIPAA Omnibus Rule makes a Business Associate's subcontractor a "Business Associate." Prior to the Rule, a business associate was responsible for getting "reasonable assurances" from its subcontractors that the subcontractors would comply with the provisions of the applicable business associate agreement. After the Rule, a Business Associate must enter into a Business Associate Agreement with each of its subcontractors. Because the subcontractor is a "Business Associate," the subcontractor must also comply with the Security Rule and some provisions of the Privacy Rule, including entering into a business associate agreement with each of its subcontractors.

Importantly, the Final Rule reaffirms that regardless of whether a Business Associate Agreement exists, one is deemed to be a business associate from the moment that person or entity creates, receives, maintains, or transmits PHI on behalf of a covered entity or another business associate.

45 CFR 160.103(4)(i) – Definitions provides that an entity including subcontractor for a CE is considered a HIPAA Business Associate (BA) if it "…creates, receives, maintains, or transmits [PHI] for a function or activity regulated by [HIPAA]" on behalf of a CE.

[ix] The BAA must meet certain standards. 45 CFR 164.504 (e)(1)(i) Standard: Business associate contracts provides:
(i) The [BAA] contract or other arrangement required by§ 164.502(e)(2) must meet the

requirements of paragraph (e)(2), (e)(3), or (e)(5) of this section, as applicable.

[x] § 164.308(a)(1)(ii)(B) Risk Management is a required implementation specification. It requires an organization to make decisions about how to address security risks and vulnerabilities. The Risk Management implementation specification states that covered entities must: "Implement security measures sufficient to reduce risks and vulnerabilities to a reasonable and appropriate level to comply with §164.306(a)."

[xi] The Office for Civil Rights (OCR) of the Department of Health and Human Services (HHS) issued on May 7, 2010, Security Rule Draft Guidance on Risk Analysis. This was the first in a "series of guidance documents [that] will assist organizations in identifying and implementing the most effective and appropriate administrative, physical, and technical safeguards to protect the confidentiality, integrity, and availability of electronic protected health information. The materials will be updated annually, as appropriate."

[xii] The required risk analysis and risk management processes at §§ 164.308(a)(1)(ii)(A) & (B) are designed to provide a foundation to guide and assist the Covered Entity to make informed decisions regarding which security measures to implement

[xiii] § 164.308(a)(1)(ii)(A) The Risk Analysis implementation specification requires covered entities to: "Conduct an accurate and thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of electronic protected health information held by the covered entity." Suggested best practices include examining: "What are the human, natural, and environmental threats to information systems that contain EPHI? "

[xiv] § 164.308(a)(1)(ii)(D) The Security Management Process standard also includes the Information System Activity Review implementation specification. This required implementation specification states that covered entities must:
"Implement procedures to regularly review records of information system activity, such

as audit logs, access reports, and security incident tracking reports."
The information system activity review enables covered entities to determine if any EPHI is used or disclosed in an inappropriate manner.

[xv] § 164.312(e)(2)(i) provides, "*Implement security measures to ensure that electronically transmitted electronic protected health information is not improperly modified without detection until disposed of*."

[xvi] § 164.312(b) provides that a covered entity must consider its risk analysis and organizational factors, such as current technical infrastructure, hardware and software security capabilities, to determine reasonable and appropriate audit controls for information systems that contain or use EPHI.

[xvii] § 164.312(b) provides "Implement hardware, software, and/or procedural mechanisms that record and examine activity in information systems that contain or use electronic protected health information."

[xviii] The Security Rule defines access in § 164.304 as "the ability or the means necessary to read, write, modify, or communicate data/information or otherwise use any system resource. (This definition applies to "access" as used in this subpart, not as used in subpart E of this part [the HIPAA Privacy Rule])." Access controls provide users with rights and/or privileges to access and perform functions using information systems, applications, programs, or files. Access controls should enable authorized users to access the minimum necessary information needed to perform job functions. Rights and/or privileges should be granted to authorized users based on a set of access rules that the covered entity is required to implement as part of § 164.308(a)(4), the Information Access Management standard under the Administrative Safeguards section of the Rule.

[xix] "Implement policies and procedures for authorizing access to electronic protected health information that are consistent with the applicable requirements of subpart E of this part [the Privacy Rule]." Restricting access to only those persons and entities with a

need for access is a basic tenet of security. By implementing this standard, the risk of inappropriate disclosure, alteration, or destruction of EPHI is minimized. Covered entities must determine those persons and/or entities that need access to EPHI within their environment.

[xx] "Implement procedures to verify that a person or entity seeking access to electronic protected health information is the one claimed."

[xxi] § 164.308(a)(5) provides that these are industry best practices.

[xxii] Covered Entities must: "Implement policies and procedures to ensure that all members of its workforce have appropriate access to electronic protected health information, as provided under [the Information Access Management standard], and to prevent those workforce members who do not have access under [the Information Access Management standard] from obtaining access to electronic protected health information."

[xxiii] Where the Authorization and/or Supervision implementation specification is a reasonable and appropriate safeguard for a covered entity, the covered entity must: "Implement procedures for the authorization and/or supervision of workforce members who work with electronic protected health information or in locations where it might be accessed." Authorization is the process of determining whether a particular user (or a computer system) has the right to carry out a certain activity, such as reading a file or running a program. Implementation of this addressable implementation specification will vary among covered entities, depending upon the size and complexity of the workforce, and the information systems that contain EPHI."

[xxiv] Covered entities need to address whether all members of the workforce with authorized access to EPHI receive appropriate clearances. Where the Workforce Clearance Procedure implementation specification is a reasonable and appropriate safeguard for a covered entity, the covered entity must:
"Implement procedures to determine that the access of a workforce member to electronic

protected health information is appropriate."

In other words, the clearance process must establish the procedures to verify that a workforce member does in fact have the appropriate access for their job function. A covered entity may choose to perform this type of screening procedure separate from or as a part of the authorization and/or supervision procedure.

[xxv] Where the Termination Procedures implementation specification is a reasonable and appropriate safeguard for a covered entity, the covered entity must:

"Implement procedures for terminating access to electronic protected health information when the employment of a workforce member ends or as required by determinations made as specified in paragraph (a)(3)(ii)(B) [the Workforce Clearance Procedure] of this section."

Termination procedures must be implemented to remove access privileges when an employee, contractor, or other individual previously entitled to access information no longer has these privileges. Whether the employee leaves the organization voluntarily or involuntarily, procedures to terminate access must be in place.

[xxvi] Joint Commission, a private group that inspects and accredits nearly 90 percent of the nation's hospitals published The Joint Commission Certification Review Process Guide : Staffing Services, 2011 – jointcommission.org The process is voluntary but is considered an important benchmark of quality and safety for insurers and patients. In order for a health care organization to participate in and receive payment from the Medicare or Medicaid programs, it must meet the eligibility requirements for program participation, including a certification of compliance with the Conditions of Participation (CoPs) or Conditions for Coverage (CfCs), which are set forth in federal regulations. The certification is based on a survey conducted by a state agency on behalf of the federal government, the Centers for Medicare & Medicaid Services (CMS) or a national accrediting organization, such as The Joint Commission, that has been approved by CMS as having standards and a survey process that meets or exceeds Medicare's requirements. Health care organizations that achieve accreditation through a Joint Commission deemed

status survey are determined to meet or exceed Medicare and Medicaid requirements.

Source:

https://www.jointcommission.org/facts_about_federal_deemed_status_and_state_recognition/